

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 412, 413, 422, and 495

[CMS-0033-P]

RIN 0938-AP78

Medicare and Medicaid Programs; Electronic Health Record Incentive Program

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would implement the provisions of the American Recovery and Reinvestment Act of 2009 (ARRA) (Pub. L. 111-5) that provide incentive payments to eligible professionals (EPs) and eligible hospitals participating in Medicare and Medicaid programs that adopt and meaningfully use certified electronic health record (EHR) technology. The proposed rule would specify the—initial criteria an EP and eligible hospital must meet in order to qualify for the incentive payment; calculation of the incentive payment amounts; payment adjustments under Medicare for covered professional services and inpatient hospital services provided by EPs and eligible hospitals failing to meaningfully use certified EHR technology; and other program participation requirements. Also, as required by ARRA the Office of the National Coordinator for Health Information Technology (ONC) will be issuing a closely related interim final rule that specifies the Secretary's adoption of an initial set of standards, implementation, specifications, and certification criteria for electronic health records. ONC will also be issuing a notice of proposed rulemaking on the process for organizations to conduct the certification of EHR technology.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on March 15, 2010.

ADDRESSES: In commenting, please refer to file code CMS-0033-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 instructions on the home page.

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-0033-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-0033-P, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

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

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue, 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, please call telephone number (410) 786-9994 in advance to schedule your arrival with one of our staff members.

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

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by following the instructions at the end of the "Collection of Information Requirements" section in this document.

In the event that CMS must limit the number of employees reporting for duty during an emergency or for other reasons, submitting comments on CMS regulations and Paperwork Reduction Act (PRA) notices via www.regulations.gov will ensure that

CMS considers the comments promptly. Comments mailed or delivered to the CMS headquarters may not be readily accessible for review if CMS employees are not able to report to work at the CMS headquarters. CMS wishes to ensure that public comments on its regulations and PRA notices are promptly displayed on the [regulations.gov](http://www.regulations.gov) Web site for the public to review. To ensure that comments are displayed as quickly as possible, we request that the public use only one public comment submission option. These efforts are intended to ensure that CMS operations continue even during an emergency and that consideration of public comments and access to those comments occur timely.

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

FOR FURTHER INFORMATION CONTACT:

Elizabeth Holland, (410) 786-1309, EHR incentive program issues. Edward Gendron, (410) 786-1064, Medicaid incentive payment issues. Jim Hart, (410) 786-9520, Medicare fee for service payment issues. Terry Kay, (410) 786-4493, Medicare fee for service payment issues.

SUPPLEMENTARY INFORMATION:

Submitting Comments: We welcome comments from the public on all issues set forth in this proposed rule to assist us in fully considering issues and developing policies. You can assist us by referencing the file code (CMS-0033-P) and the specific "issue identifier" that precedes the section on which you choose to comment.

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
 CAH Critical Access Hospital
 CAHPS Consumer Assessment of Healthcare Providers and Systems
 CCN CMS Certification Numbers
 CHIP Children's Health Insurance Program
 CHIPRA Children's Health Insurance Program Reauthorization Act of 2009
 CMS Centers for Medicare & Medicaid Services
 CY Calendar Year
 EHR Electronic Health Record
 EP Eligible Professionals
 EPO Exclusive Provider Organization
 FACA Federal Advisory Committee Act
 FFP Federal Financial Participation
 FFS Fee-For-Service
 FQHC Federally Qualified Health Center
 FTE Full-Time Equivalent
 FY Fiscal Year
 FFY Federal Fiscal Year
 HEDIS Healthcare Effectiveness Data and Information Set
 HHS Department of Health and Human Services
 HIE Health Information Exchanges
 HIT Health Information Technology
 HIPPA 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 Services Administration
 IAPD Implementation Advanced Planning Document
 IPA Independent Practice Association
 IHS Indian Health Services
 IT Information Technology
 MA Medicare Advantage
 MAC Medicare Administrative Contractor
 MCO Medicaid Managed Care Organization
 MITA Medicaid Information Technology Architecture
 MMIS Medicaid Management Information Systems
 MSA Medical Savings Account
 NCQA National Committee for Quality Assurance
 NCVHS National Committee on Vital and Health Statistics
 NPI National Provider Identifier
 ONC Office of the National Coordinator for Health Information Technology
 PAHP Prepaid Ambulatory Health Plan
 PAPD Planning Advanced Planning Document
 PIHP Prepaid Inpatient Health Plan
 PFFS Private Fee-For-Service
 PHO Physician Hospital Organization
 PHS Public Health Service
 POS Place of Service
 PPO Preferred Provider Organization
 PSO Provider Sponsored Organization
 RHC Rural Health Clinic
 RPPO Regional Preferred Provider Organization
 SMHP State Medicaid Health Information Technology Plan
 TIN Tax Identification Number

Table of Contents

I. Background	b. Methods for Demonstration of the Stage 1 Criteria of Meaningful Use
A. Overview of the HITECH Programs Created by the American Recovery and Reinvestment Act of 2009	5. Data Collection for Online Posting, Program Coordination and Accurate Payments
B. Statutory Basis for the Medicare & Medicaid EHR Incentive Programs	a. Online Posting
II. Provisions of the Proposed Regulations	b. Program Election Between Medicare FFS/MA and Medicaid for EPs
A. Definitions Across the Medicare FFS, Medicare Advantage, and Medicaid Programs	c. Data To Be Collected
1. Definitions	6. Hospital-Based Eligible Professionals
a. Certified Electronic Health Record (EHR) Technology	7. Interaction With Other Programs
b. Qualified Electronic Health Record	B. Medicare Fee-for-Service Incentives
c. Payment Year	1. Incentive Payments for Eligible Professionals
d. First, Second, Third, Fourth, Fifth and Sixth Payment Year	a. Definitions
e. EHR Reporting Period	b. Incentive Payment Limits
f. Meaningful EHR User	c. Increase in Incentive Payment for EPs who Predominantly Furnish Services in a Geographic Health Professional Shortage Area
2. Definition of Meaningful Use	d. Form and Timing of Payment
a. Background	e. Payment Adjustment Effective in CY 2015 and Subsequent Years for EPs Who Are Not Meaningful Users of Certified EHR Technology
b. Common Definition of Meaningful Use Under Medicare and Medicaid	2. Incentive Payments for Hospitals
c. Considerations in Defining Meaningful Use	a. Definition of Eligible Hospital for Medicare
d. Stage 1 Criteria for Meaningful Use	b. Incentive Payment Calculation for Eligible Hospitals
3. Sections 4101(a) and 4102(a)(1) of HITECH Act: Reporting on Clinical Quality Measures Using EHR by EPs and All Eligible Hospitals	c. Medicare Share
a. General	d. Charity Care
b. Requirements for the Submission of Clinical Quality Measures by EPs and Eligible Hospitals	e. Transition Factor
c. Statutory Requirements and Other Considerations for the Proposed Selection of Clinical Quality Measures Proposed for Electronic Submission by EPs or Eligible Hospitals	f. Duration and Timing of Incentive Payments
(1) Statutory Requirements for the Selection of Clinical Quality Measures Proposed for Electronic Submission by EPs and Eligible Hospitals	g. Incentive Payment Adjustment Effective in Federal FY 2015 and Subsequent Years for Eligible Hospitals Who Are Not Meaningful EHR Users
(2) Other Considerations for the Proposed Selection of Clinical Quality Measures for Electronic Submission by EPs and Eligible Hospitals	3. Incentive Payments for Critical Access Hospitals
d. Proposed Clinical Quality Measures for Electronic Submission Using Certified EHR Technology by Eligible Professionals	a. Definition of CAHs for Medicare
e. Clinical Quality Measures Reporting Criteria for Eligible Professionals	b. Current Medicare Payment of Reasonable Cost for CAHs
f. Proposed Clinical Quality Measures for Electronic Submission by Eligible Hospitals	c. Changes made by the HITECH Act
g. Request for Public Comment on Potential Measures for Eligible Professionals and Eligible Hospitals in 2013 Payment Year and Subsequent Years	d. Incentive Payment Calculation for CAHs
h. Proposed Reporting Method for Clinical Quality Measures	e. Reduction of Reasonable Cost Payment in FY 2015 and Subsequent Years for CAHs That Are Not Meaningful EHR Users
(1) Reporting Method for 2011 Payment Year	4. Process for Making Incentive Payments Under the Medicare FFS Program
(2) Reporting Method for 2012	a. Incentive Payments to EPs
i. Alternative Reporting Methods for Clinical Quality Measures	b. Incentive Payments to Eligible Hospitals
j. Proposed Reporting Criteria for Eligible Professionals and Eligible Hospitals	c. Incentive Payments to CAHs
k. Addressing Dually-Eligible Medicare/Medicaid Beneficiaries Under HITECH	d. Payment Accounting under Medicare
4. Demonstration of Meaningful Use	C. Medicare Advantage Organization Incentive Payments
a. Common Methods of Demonstration in Medicare and Medicaid	1. Definitions
	a. Qualifying MA Organization
	b. Qualifying MA Eligible Professional
	c. Qualifying MA-Affiliated Eligible Hospital
	2. Identification of Qualifying MA Organizations, MA EPs, and MA-Affiliated Eligible Hospitals
	3. Computation of Incentives to Qualifying MA Organizations for MA EPs and Hospitals
	4. Timeframe for Payment
	5. Avoiding Duplicate Payment
	6. Meaningful User Attestation
	7. Posting on Web site and Limitation on Review
	8. Limitation on Review
	9. Conforming Changes

10. Payment Adjustment and Future Rulemaking
 - D. Medicaid Incentives
 1. Overview of Health Information Technology in Medicaid
 2. General Medicaid Provisions
 3. Identification of Qualifying Medicaid EPs and Eligible Hospitals
 - a. Overview
 - b. Program Participation
 1. Acute Care Hospitals
 2. Children's Hospitals
 - c. Medicaid Professionals Program Eligibility
 - d. Calculating Patient Volume Requirements
 - e. Entities Promoting the Adoption of Certified EHR Technology
 4. Computation of Amount Payable to Qualifying Medicaid EPs and Eligible Hospitals
 - (1) General Overview
 - (2) Average Allowable Costs
 - (3) Net Average Allowable Costs
 - (4) Payments for Medicaid Eligible Professionals
 - (5) Basis for Medicaid EHR Incentive Program First Payment Year and Subsequent Payment Years
 - (i) Medicaid EP Who Begins Adopting, Implementing or Upgrading Certified EHR Technology in the First Year
 - (ii) Medicaid EP who has Already Adopted, Implemented or Upgraded Certified EHR Technology and Meaningfully Uses EHR Technology
 - b. Payment Methodology for Eligible Hospitals
 - c. Alternative and Optional Early State Implementation to Make Incentive Payments for Adopting, Implementing or Upgrading Certified EHR Technology
 - d. Process for Making and Receiving Medicaid Incentive Payments
 - e. Avoiding Duplicate Payment
 - f. Flexibility to Alternate Between Medicare and Medicaid Incentive Payment Program One Time
 - g. One State Selection
 5. National Level Repository and State Data Collection
 6. Collection of Information Related to the Eligible Professional's National Provider Identifier and the Tax Identification Number (TIN)
 7. Activities Required to Receive Incentive Payments
 - a. General Overview
 - b. Definitions Related to Certified EHR Technology and Adopting, Implementing or Upgrading Such Technology
 - (1) Certified EHR Technology
 - (2) Adopting, Implementing or Upgrading
 - c. Other General Terminology
- III. Collection of Information Requirements
 - A. ICRs Regarding Demonstration of Meaningful Use Criteria (§ 495.8)
 - B. ICRs Regarding Participation Requirements for EPs, Eligible Hospitals, and Qualifying CAHs (§ 495.10)
 - C. ICRs Regarding Identification of Qualifying MA Organizations, MA-EPs and MA-Affiliated Eligible Hospitals (§ 495.202)
 - D. ICRs Regarding Incentive Payments to Qualifying MA Organizations for MA-EPs and Hospitals (§ 495.204)

- E. ICRs Regarding Meaningful User Attestation (§ 495.210)
- F. ICRs Regarding Incentive Payments to Qualifying MA Organizations for MA-Eligible Professionals and Hospitals (§ 495.220)
- G. ICRs Regarding Process for Payments (§ 495.312)
- H. ICRs Regarding Activities Required to Receive an Incentive Payment (§ 495.314)
- I. ICRs Regarding State Monitoring and Reporting Regarding Activities Required To Receive an Incentive Payment (§ 495.316)
- J. ICRs Regarding State Responsibilities for Receiving FFP (§ 495.318)
- K. ICRs Regarding Prior Approval Conditions (§ 495.324)
- L. ICRs Regarding Termination of Federal Financial Participation (FFP) for Failure To Provide Access to Information (§ 495.330)
- M. ICRs Regarding State Medicaid Agency and Medicaid EP and Hospital Activities (§ 495.332 Through § 495.338)
- N. ICRs Regarding Access to Systems and Records (§ 495.342)
- O. ICRs Regarding Procurement Standards (§ 495.344)
- P. ICRs Regarding State Medicaid Agency Attestations (§ 495.346)
- Q. ICRs Regarding Reporting Requirements (§ 495.348)
- R. ICRs Regarding Retroactive Approval of FFP With an Effective Date of February 18, 2009 (§ 495.358)
- S. ICRs Regarding Financial Oversight and Monitoring Expenditures (§ 495.362)
- T. ICRs Regarding Appeals Process for a Medicaid Provider Receiving Electronic Health Record Incentive Payments (§ 495.366)
- IV. Response to Comments
- V. Regulatory Impact Analysis
 - A. Overall Impact
 - B. Regulatory Flexibility Analysis
 - C. Small Rural Hospitals
 - D. Unfunded Mandates Reform Act
 - E. Federalism
 - F. Anticipated Effects
 - G. HITECH Impact Analysis
 - H. Accounting Statement

I. Background

A. 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) was enacted on February 17, 2009. ARRA includes many measures to modernize our nation's infrastructure, enhance energy independence, expand educational opportunities, provide tax relief, and preserve and improve affordable health care. Title IV of Division B of ARRA amends Titles XVIII and XIX of the Social Security Act (the Act) by establishing incentive payments to eligible professionals (EPs) and eligible hospitals to promote the adoption and meaningful use of interoperable health information

technology and qualified EHRs. Expanded use of health information technology (HIT) and EHRs will improve the quality and value of American health care. These provisions, together with Title XIII of Division A of ARRA, may be cited as the Health Information Technology for Economic and Clinical Health Act" or the "HITECH Act." The incentive payments for adoption and meaningful use of HIT and qualified EHRs are part of a broader effort under the HITECH Act to accelerate the adoption of HIT and utilization of qualified EHRs. We are developing the incentive programs which are outlined in Division B, Title IV of the HITECH Act and these programs are the keys to inducing providers to actively utilize HIT.

EPs and eligible hospitals qualify for the EHR incentive payments if, among other requirements, they meaningfully use certified EHR technology. This proposed rule sets forth a proposed definition of "meaningful use of certified EHR technology." Section 13101 of the HITECH Act adds a new section 3000 to the Public Health Service Act (PHSA), which defines "certified EHR technology" as a qualified EHR that has been properly certified as meeting standards adopted under section 3004 of the PHSA. CMS and ONC have been working closely to ensure that the definition of meaningful use of certified EHR technology and the standards for certified EHR technology are coordinated. "Meaningful use" is a term defined by CMS and describes the use of HIT that furthers the goals of information exchange among health care professionals. In an upcoming interim final rule, ONC will identify the initial set of standards and implementation specifications that EHR technology must implement, as well as the certification criteria that will be used to certify EHR technology, and will further define the term "certified EHR technology." In a related proposed rule, the Department will propose the development of a certification program for health IT. Specifically, we have sought to ensure that the definition of meaningful use of certified EHR technology does not require EPs and eligible hospitals to perform functionalities for which standards have not been recognized or established. Similarly, the functionality of certified EHR technology should enable and advance the definition of meaningful use.

We urge those interested in this proposed rule to also review the ONC interim final rule with comment and the related proposed rule when they are published later this year and to visit <http://healthit.hhs.gov> and <http://>

www.cms.hhs.gov/Recovery/11_HealthIT.asp#TopOfPage for more information on the efforts at the Department of Health and Human Services (HHS) to advance HIT initiatives.

B. Statutory Basis for the Medicare & Medicaid EHR Incentive Programs

Section 4101(a) of the HITECH Act adds a new subsection (o) to section 1848 of the Act. Section 1848(o) of the Act establishes incentive payments for the meaningful use of certified EHR technology by EPs participating in the original Medicare program or hereinafter referred to as Medicare Fee-for-Service (FFS) program beginning in calendar year (CY) 2011. Section 4101(b) of the HITECH Act also adds a new paragraph (7) to section 1848(a) of the Act. Section 1848(a)(7) of the Act provides that beginning in CY 2015, EPs who are not meaningful users of certified EHR technology will receive less than 100 percent of the fee schedule for their professional services. Section 4101(c) of the HITECH Act adds a new subsection (l) to section 1853 of the Act to provide incentive payments to Medicare Advantage (MA) organizations for their affiliated EPs who meaningfully use certified EHR technology and meet certain other requirements, and a requirement to make a downward adjustment to Medicare payments to MA organizations for professional services provided by any of their affiliated EPs who are not meaningful users of certified EHR technology, beginning in 2015, and avoids duplicate of payments from the MA EHR incentive program under this section and the FFS EHR incentive program under section 1848(o)(1)(A).

Section 4102(a) of the HITECH Act adds a new subsection (n) to section 1886 of the Act. Section 1886(n) of the Act establishes incentive payments for the meaningful use of certified EHR technology by subsection (d) hospitals, as defined under section 1886(d)(1)(B) of the Act, participating in Medicare FFS program beginning in Federal fiscal year (FY) 2011. Section 4102(b)(1) of the HITECH Act amends section 1886(b)(3)(B) of the Act to provide that, beginning in FY 2015, subsection (d) hospitals that are not meaningful users of certified EHR technology will receive a reduced annual payment update. Section 4102(b)(2) of the HITECH Act amends section 1814(l) of the Act to provide an incentive payment to critical access hospitals (CAHs) who meaningfully use certified EHR technology based on the hospitals' reasonable cost beginning in FY 2011. In addition, section 4102(a)(2) of the

HITECH Act amends section 1814(l) of the Act to provide for a downward payment adjustment for hospital services provided by CAHs that are not meaningful users of certified EHR technology for cost reporting periods beginning in FY 2015. Section 4102(c) of the HITECH Act adds a new subsection (m) to section 1853 of the Act to provide incentive payments to MA organizations for certain affiliated hospitals that meaningfully use certified EHR technology to address avoidance of duplicate payments, and to make a downward adjustment to payments to MA organizations for inpatient hospital services provided by its affiliated hospitals that are not meaningful users of certified EHR technology beginning in FY 2015.

Section 4103 of the HITECH Act provides for implementation funding for the EHR incentives program under Medicare.

Section 4201 of the HITECH Act amends section 1903 of the Act to provide 100 percent Federal financial participation (FFP) to States for incentive payments to certain eligible providers participating in the Medicaid program to purchase, implement, and operate (including support services and training for staff) certified EHR technology and 90 percent FFP for State administrative expenses related to the program outlined in 1903(t) of the Act. Section 4201(a)(2) of the HITECH Act adds a new subsection (t) to section 1903 of the Act to establish a program with input from the States to provide incentives for the adoption and subsequent meaningful use of certified EHR technology for providers participating in the Medicaid program.

II. Provisions of the Proposed Regulations

We propose to add a new part 495 to title 42 of the Code of Federal Regulations to implement the provisions discussed in this section of the proposed rule related to certified EHR technology for providers participating in either the Medicare program or the Medicaid program.

The HITECH Act creates incentives in the Medicare Fee-for-Service (FFS), Medicare Advantage (MA), and Medicaid programs for demonstrating meaning EHR use and payment adjustments in the Medicare FFS and MA programs for not demonstrating meaningful EHR use. The three incentive programs contain many common elements and certain provisions of the HITECH Act encourage avoiding duplication of payments, reporting, and other requirements, particularly in the area of demonstrating

meaningful use of certified EHR technology. Eligible hospitals may participate in either one of the Medicare (FFS or MA) programs and the Medicaid program, assuming they meet each program's eligibility requirements, which vary across programs. In certain cases, the HITECH Act has used nearly identical or identical language in defining terms that are used in the Medicare FFS, MA, and Medicaid programs, including such terms as "hospital-based EPs" and "certified EHR technology." In these cases, we seek to create as much commonality between the three programs as possible and have structured this proposed rule based on that premise by beginning with those provisions that cut across the three programs before moving on to discuss the provisions specific to Medicare FFS, MA and Medicaid.

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

Title IV, Division B of the HITECH Act establishes incentive payments under the Medicare and Medicaid programs for certain professionals and hospitals that meaningfully use certified EHR technology. Under Medicare, these incentive payments may be made to qualifying professionals, hospitals, and Medicare Advantage (MA) organizations on behalf of certain MA affiliated physicians and hospitals. We refer to the incentive payments made under the original Medicare program as the Medicare FFS EHR incentive program. We refer to the incentive payments made to qualifying MA organizations as the MA EHR incentive program, and the incentive payments made under Medicaid as the Medicaid EHR incentive program. When referring to Medicare EHR incentive program, we are referring to both the Medicare FFS EHR and the MA EHR incentive programs.

1. Definitions

Sections 4101, 4102, and 4202 of the HITECH Act use many identical or similar terms. In this section of the preamble, we discuss terms for which we are proposing uniform definitions for the Medicare FFS, Medicare Advantage, and Medicaid EHR incentive programs. These definitions would be included in part 495 subpart A of the regulations. For definitions specific to an individual program, the definition is set forth and discussed in the applicable EHR incentive program section.

a. Certified Electronic Health Record (EHR) Technology

The incentive payments are available to EPs (non-hospital-based physicians, as defined in section 1861(r) of the Act, who either receive reimbursement for services under the Medicare FFS program or have an employment or contractual relationship with a qualifying MA organization meeting the criteria under section 1853(l)(2) of the Act; or healthcare professionals meeting the definition of “eligible professional” under section 1903(t)(3)(B) of the Act as well as the patient-volume and non-hospital-based criteria of section 1903(t)(2)(A) of the Act) and eligible hospitals (subsection (d) hospitals as defined under subsection 1886(d)(1)(B) of the Act that either receive reimbursement for services under the Medicare FFS program or are affiliated with a qualifying MA organization as described in section 1853(m)(2) of the Act; critical access hospitals (CAHs); or acute care or children’s hospitals described under section 1903(t)(2)(B) of the Act). Under all three EHR incentive programs, EPs and eligible hospitals must utilize “certified EHR technology” if they are to be considered eligible for the incentive payments. In the Medicare FFS EHR incentive program this requirement for EPs is found in section 1848(o)(2)(A)(i) of the Act, as added by section 4101(a) of the HITECH Act, and for eligible hospitals and CAHs in section 1886(3)(A)(i) of the Act, as added by section 4102(a) of the HITECH Act. In the MA EHR incentive program this requirement for EPs is found in section 1853(l)(1) of the Act, as added by section 4101(c) of the HITECH Act, and for eligible hospitals and CAHs, in section 1853(m)(1) of the Act, as added by section 4201(c) of the HITECH Act. In the Medicaid EHR incentive program this requirement for EPs and Medicaid eligible hospitals is found throughout section 1903(t) of the Act, including in section 1903(t)(6)(C) of the Act, as added by section 4201(a)(2) of the HITECH Act. While certified EHR technology is a critical component of the EHR incentive programs, under the authority given to her in the HITECH Act, the Secretary has charged ONC with developing the criteria and mechanisms for certification of EHR technology. Therefore, ONC will be defining certified EHR technology in its upcoming interim final rule and we propose to use the definition of certified EHR technology adopted by ONC.

b. Qualified Electronic Health Record

In order for an EHR technology to be eligible for certification it must first

meet the definition of a qualified electronic health record. This term will be defined by ONC in its upcoming interim final rule, and we propose to use the definition of qualified electronic health record adopted by ONC.

c. Payment Year

Under section 1848(o)(1)(A)(i) of the Act, as added by section 4101(a) of the HITECH Act, the Medicare FFS EHR incentive payment is available to EPs for a “payment year.” Section 1848(o)(1)(E) of the Act defines the term “payment year” as a year beginning with 2011. While the HITECH Act does not use the term, “payment year,” for the Medicaid EHR incentive program, it does use the term “year of payment” throughout section 1903(t) of the Act, for example, at sections 1903(t)(3)(C), 1903(t)(4)(A), and 1903(t)(6)(C) of the Act. For all EPs, we are proposing a common definition for both “payment year” and “year of payment,” as “any calendar year beginning with 2011” at § 495.4. (The only exception to this rule, is that in certain cases, Medicaid EPs would be able to participate in the Medicaid EHR incentive program starting with CY 2010, for adopting, implementing, or upgrading certified EHR technology. For further discussion of this early participation in the Medicaid EHR incentive program, we refer readers to section II.D.3.c. of this proposed rule.)

This definition, which is consistent with the statutory definition of “payment year” under Medicare FFS, will simplify the EHR incentive programs for EPs. As discussed later in this preamble, EPs may have the opportunity to participate in either the Medicare or Medicaid incentive programs, and once an EP has picked a program, they are permitted to make a one-time switch from one program to the other. A common definition will allow EPs to more easily understand both programs, and inform decisions regarding whether they are eligible for, and/or wish to participate in either program. Under section 1886(n)(1) of the Act, as added by section 4102(a) of the HITECH Act, the Medicare FFS EHR incentive payment is available to eligible hospitals and CAHs for a “payment year.” Section 1886(n)(2)(G) of the Act defines the term “payment year” as a fiscal year (FY) beginning in 2011. As hospitals are paid based on the 12-month Federal fiscal year, we believe the reference to a “fiscal year” means the fiscal year beginning on October 1 of the prior year and extending to September 30 of the relevant year. Again, for the Medicaid EHR incentive program, the HITECH Act uses the term, “year of payment” (see section 1903(t)(5)(D)(ii)

of the Act), rather than “payment year.” For the same reasons expressed above for EPs, and because hospitals will have the opportunity to simultaneously participate in both the Medicare and Medicaid EHR incentive programs, we propose a common definition of “payment year” and “year of payment” for both programs. For purposes of the incentive payments made to eligible hospitals under the Medicare FFS, MA and Medicaid EHR incentive programs, we propose to define payment year and year of payment at § 495.4, consistent with the statutory definition, as “any fiscal year beginning with 2011”. (The only exception to this rule, is that in certain cases, Medicaid eligible hospitals would be able to participate in the Medicaid EHR incentive program starting with FY 2010, for adopting, implementing, or upgrading certified EHR technology. For further discussion of this early participation in the Medicaid EHR incentive program, we refer readers to section II.D.3.c of this proposed rule.)

The actual timing of the incentive payment for a given payment year varies depending on which EHR incentive program an EP or an eligible hospital is participating in. Details on the timing of incentive payments for a given payment year can be found in section II.B. of the proposed rule for Medicare FFS, section II.C. of the proposed rule for MA and section II.D. of the proposed rule for Medicaid.

d. First, Second, Third, Fourth, Fifth, and Sixth Payment Year

For EPs and eligible hospitals that qualify for EHR incentive payments in a payment year, the amount of the payment will depend in part on how many previous payment years, if any, an EP or eligible hospital received an incentive payment. We propose to define the first payment year to mean the first calendar or Federal fiscal year for which an EP or eligible hospital receives an incentive payment. Likewise, we propose to define the second, third, fourth, fifth, and sixth payment year, respectively, to mean the second, third, fourth, fifth, and sixth calendar or Federal fiscal year, respectively, for which an EP or eligible hospital receives an incentive payment.

e. EHR Reporting Period

In order to qualify for an incentive payment under the Medicare incentive payment program for a payment year, an EP or eligible hospital must meaningfully use certified EHR technology for the EHR reporting period of the relevant payment year. Similarly, a Medicaid EP or eligible hospital may

in the first payment year and must in subsequent payment years demonstrate meaningful use of such technology, in order to receive a payment. A Medicaid EP or eligible hospital may receive an incentive payment in their first payment year for the adoption, implementation, or upgrade of certified EHR technology. Although the Medicaid statute does not specifically use the term, "EHR reporting period," we believe that the Secretary, pursuant to sections 1903(t)(6)(C) and 1903(t)(8) of the Act, has the authority to define the period that would be used for demonstrating such adoption/implementation/upgrade or meaningful use.

In this proposed rule, we propose a definition of EHR Reporting Period for purposes of the Medicare and Medicaid incentive payments under sections 1848(o), 1853(l)(3), 1886(n), 1853(m)(3), 1814(l) and 1903(t) of the Act. For these sections, the EHR reporting period may be any continuous 90-day period within the first payment year and the entire payment year for all subsequent payment years. In future rulemaking, we will propose a definition of EHR Reporting Period for purposes of Medicare incentive payment adjustments under sections 1848(a)(7), 1853(l)(4), 1886(b)(3)(B)(ix), 1853(m)(4), and 1814(l)(4) of the Act. Unlike the former group of sections, meaningful EHR users that would not be subject to adjustments would have to be identified prior to the application of the latter group of sections. Therefore, these two groups of sections may have two different definitions of EHR Reporting Period.

For the first payment year only, we propose to define the term EHR reporting period at § 495.4 to mean any continuous 90-day period within a payment year in which an EP or eligible hospital successfully demonstrates meaningful use of certified EHR technology. The EHR reporting period therefore could be any continuous period beginning and ending within the relevant payment year. For example, for payment year 2011, an EHR reporting period of March 13, 2011 to June 11, 2011 would be just as valid as an EHR reporting period of January 1, 2011 to April 1, 2011. An example of an unallowable EHR reporting period would be for an EP to begin on November 1, 2011 and finish on January 31, 2012. Starting with the second payment year and any subsequent payment years for a given EP or eligible hospital, we propose to define the term EHR reporting period at § 495.4 to mean the entire payment year.

In defining the EHR reporting period, we considered three of its aspects:

(1) Whether it should vary from one payment year to the next; (2) its length; and (3) starting point. We discuss these three aspects below.

The first aspect of the EHR reporting period discussed is whether it should be the same for each payment year. We believe that there are considerations that distinguish the first payment year from the remaining payment years. The foremost being that once an EP or eligible hospital begins to meaningfully use certified EHR technology they are unlikely to stop. As discussed below, in the first payment year a shorter EHR reporting period would provide more flexibility for when an EP or eligible hospital begins to meaningfully use certified EHR technology and still qualify for the incentive in the same year. However, in subsequent years we do not see that flexibility still being required. Therefore, for purposes of the incentive payments under sections 1848(o), 1853(l)(3), 1886(n), 1853(m)(3), 1814(l), and 1903(t) of the Act, we propose that the length of the EHR reporting period be different for the first payment year than from all other payment years. We invite interested parties to comment on this proposal if they believe that the EHR reporting period should vary from payment year to payment year.

With respect to the length of the EHR reporting period, we note that there is an inherent tradeoff between robust verification and time available to achieve compliance. A longer EHR reporting period provides a more robust verification that an EP or eligible hospital successfully met the definition of meaningful use of certified EHR technology than a shorter period. However, it reduces the time available for an EP or eligible hospital to reach the point of complying with meaningful use and still receive an incentive for a given payment year. For example, a 90-day period would allow an EP until October 1, 2011 to begin meaningful use of their certified EHR technology and receive an incentive for payment year 2011. A 180-day period (6 months) would move the date upon which the EP must begin meaningful use of their certified EHR technology forward to July 1, 2011. We are concerned that an EHR reporting period that is shorter than 90 days would be insufficient time to ensure that EPs and eligible hospitals are truly using certified EHR technology in a meaningful manner consistent with our proposed criteria for meaningful use. Moreover, as discussed later in this proposed rule, we will require EPs and hospitals to demonstrate meaningful use by meeting certain performance thresholds (for example, EPs will need

to use CPOE for 80 percent of all orders, and hospitals for 10 percent of all orders). We believe a period of fewer than 90 days would not be adequate to create an accurate rate for a given EP or eligible hospital. We believe that once an EP or hospital has implemented certified EHR technology to the point of being able to comply with our proposed meaningful use criteria for 90 days, it is unlikely that they would adjust their behavior just because the EHR reporting period has ended. Beginning in the second payment year, an EP or eligible hospital will already be meaningfully using certified EHR technology so there are no limitations on the time available for compliance.

For the first payment year, therefore, we propose that the EHR reporting period will be any continuous 90-day period within the first payment year. However, beginning in the second payment year we see no compelling reason not to seek the most robust verification possible. Therefore for the second payment year and all subsequent payment years we propose the EHR reporting period be the entire payment year. As the length of the EHR reporting period is based on the discussed trade-off, we remain open to alternative lengths of time. We invite comments on the appropriate length for the EHR reporting period. We urge those commenting to either endorse our proposed initial 90-day period followed by full year EHR reporting periods or to recommend a specific alternative.

With respect to when the EHR reporting period for a payment year should begin, there are two considerations. The first is determining the earliest start date available, and the second is the flexibility given to EPs and eligible hospitals to choose their start date. This aspect is only applicable for the 90-day EHR reporting period for the first payment year. The length of the EHR reporting period for the second payment year and subsequent payment years dictate that the start date be the first day of the payment year. The earliest start date we considered was one which would allow an EP or eligible hospital to demonstrate successful meaningful use of certified EHR technology on the first day of the relevant payment year. For example, allowing an EHR reporting period to begin as early as July 3, 2010 would allow an eligible hospital to successfully demonstrate meaningful use on October 1, 2010, the first day of FY 2011. We have chosen not to propose this as the earliest start date. There are significant barriers created by the timeline in the HITECH Act. We anticipate that we will not publish a final rule until after March

2010, with the final rule effective 60 days after its publication. We do not believe this allows enough time for us, the vendor community, or the provider community to take advantage of this early start date. In addition, as discussed at sections 1848(o)(2)(B)(iii) and 1886(n)(3)(B)(iii) of the Act, the HITECH Act directs the Secretary to seek to avoid duplicative reporting of clinical quality and other measures under the Medicare EHR incentive program and other Medicare programs. If we were to allow EPs and hospitals to report these measures to CMS prior to the beginning of the FY, this reporting may be of questionable value to other Medicare programs requiring reporting of the same measures. For example, if and when the demonstration of meaningful use includes the submission of quality measures this submission could include measures currently in the RHQDAPU program. As discussed in section II.A.3. of this proposed rule, we do not desire to have a hospital report the same measure twice for two different programs. However, if a hospital reports these measures from July through September 2010 for payment year 2011 for Medicare and/or Medicaid EHR incentive program, they would not be relevant for FY 2011 under the RHQDAPU. Due to the operational challenges presented and the statutory requirement to avoid duplication of payments to the extent possible, we are proposing that the earliest start date for EHR reporting period be the first day of the payment year. The second consideration for when the EHR reporting period should begin is whether to designate specific start dates. As we are not aware of any compelling reason to limit the start dates available to EPs or eligible hospitals within the payment year, we propose to allow EPs or eligible hospitals to begin their EHR reporting period on any date starting with the first day of the payment year and ending with the latest day in the payment year that allows for the EHR reporting period to be completed by the last day of the payment year. We believe that giving EPs and eligible hospitals flexibility as to the start date of the EHR reporting is important, as unforeseen circumstances, such as delays in implementation, higher than expected training needs and other unexpected hindrances, may cause an EP or eligible hospital to potentially miss a target start date. We invite comments on the proposed start dates for the EHR reporting period.

We acknowledge that all three of these aspects will be affected by the need to determine which physicians,

hospitals, critical access hospitals and managed care plans are meaningful users before application of the Medicare payment adjustments (provisions of sections 1848(a)(7), 1853(l)(4), 1886(b)(3)(B)(ix), 1853(m)(4), and 1814(l)(4) of the Act). We will specify the EHR reporting periods for these payment adjustment incentives in future rulemaking.

f. Meaningful EHR User

Section 1848(o)(1)(A)(i) of the Act, as added by section 4101(a) of the HITECH Act, limits incentive payments in the Medicare FFS EHR incentive program to an EP who is a "meaningful EHR user." Section 1886(n)(1) of the Act, as added by section 4102(a) of the HITECH Act, limits incentive payments in the Medicare FFS EHR incentive program to hospitals described in section 1886(d) of the Act. Section 1814(l) of the Act limits incentive payments in the Medicare FFS EHR incentive program to CAHs who are "meaningful EHR users." Section 1903(t)(6)(C)(i)(II) of the Act, as added by section 4201(a)(2) of the HITECH Act, limits incentive payments for payment years other than the first payment year to a Medicaid provider who "demonstrates meaningful use of certified EHR technology." We propose to define at § 495.4 the term "meaningful EHR user" as an EP or eligible hospital who, for an EHR reporting period for a payment year, demonstrates meaningful use of certified EHR technology in the form and manner consistent with our standards (discussed below). These standards would include use of certified EHR technology in a manner that is approved by us.

2. Definition of Meaningful Use

a. Background

As discussed previously, an EP or eligible hospital must be a meaningful EHR user in order to receive the incentive payments available under the EHR incentive programs, except in the first payment year for certain Medicaid EPs or eligible hospitals. This section (II.A.2.) of this proposed rule discusses the definition of meaningful use. Section II.A.3. of this proposed rule, discusses the manner for demonstrating meaningful use. In Sections 1848(o)(2)(A) and 1886(n)(3) of the Act, the Congress specified three types of requirements for meaningful use: (1) Use of certified EHR technology in a meaningful manner (for example, electronic prescribing); (2) that the certified EHR technology is connected in a manner that provides for the electronic exchange of health information to improve the quality of

care; and (3) that, in using certified EHR technology, the provider submits to the Secretary information on clinical quality measures and such other measures selected by the Secretary.

Over the last few months, CMS and ONC have solicited input on defining meaningful use from both other government agencies and the public through dialogue, public forums, and solicitation of written comments. Below we describe the work of the National Committee on Vital and Health Statistics (NCVHS), the HIT Standards Committee and the HIT Policy Committee, as well as the public input we have received on defining meaningful use.

The NCVHS is the Department of Health and Human Services' statutory public advisory body on health data, statistics, and national health information policy. NCVHS derives its authority from 42 U.S.C. 242k, section 306(k) of the Public Health Service Act, which governs it along with the provisions of Public Law 92-463 (5 U.S.C. App.2). The full charter and membership of the NCVHS is available electronically at <http://www.ncvhs.hhs.gov/>. The NCVHS held a public hearing on April 28 and 29, 2009 to learn from a broad spectrum of stakeholders their views of "meaningful use." The NCVHS hearing brought together key healthcare and information technology stakeholder groups including: Representatives of patients, and more broadly consumers; providers; the public health community; public and private payers; vendors; and certifying entities. The hearing agenda and testimony supplied is available electronically at <http://www.ncvhs.hhs.gov/090428ag.htm>. A report on the hearing was delivered May 15, 2009 to the ONC. The report is available electronically at <http://www.ncvhs.hhs.gov/090518rpt.pdf>. Written comments from interested stakeholders submitted timely to the NCVHS were also considered by the NCVHS Executive Sub-Committee in the drafting of the report. Subsequently, the National Coordinator for HIT requested NCVHS to reflect on the testimony by supplying observations. Those observations are available electronically at <http://www.ncvhs.hhs.gov/090428rpt.pdf>.

In addition to the work completed by the NCVHS, the HIT Policy Committee, a Federal Advisory Committee to the Department of Health and Human Services (HHS) created by the HITECH Act, also worked to inform the definition of meaningful use. The full charter and membership of the HIT Policy Committee can be found at

<http://healthit.hhs.gov>. The HIT Policy Committee formed a Meaningful Use workgroup. On June 16, 2009, the HIT Policy Committee heard and discussed the recommendations from their Meaningful Use workgroup, and subsequently submitted its own recommendations on meaningful use to the National Coordinator for Health IT. These recommendations are available electronically at <http://healthit.hhs.gov>. At the conclusion of the June 16 meeting, ONC announced a public comment period to solicit stakeholder input on the recommendations and published a notice in the **Federal Register** (74 FR 28937). The public comment period lasted through June 26, 2009. Over 700 public comments were received by the ONC. A summary, as well as the text of the comments, is available electronically at <http://healthit.hhs.gov>. The Meaningful Use workgroup presented its revised recommendations to the full committee based on comments by the full HIT Policy Committee and by the public at the July 16, 2009 meeting. In developing its recommendations, the HIT Policy Committee considered a report entitled "National Priorities and Goals" (<http://www.nationalprioritiespartnership.org/uploadedFiles/NPP/08-253-NQF%20ReportLo%5b6%5d.pdf>) generated by the National Priorities Partnership, convened by the National Quality Forum (NQF). Of the national health care priorities set forward by the NQF report, the HIT Policy Committee chose as priority areas patient engagement; reduction of racial disparities; improved safety; increased efficiency; coordination of care; and improved population health to drive their recommendations. Those recommendations are available electronically at <http://healthit.hhs.gov>.

The HIT Standards Committee, another Federal Advisory Committee created by the HITECH Act, provided recommendations related to meaningful use to ONC. The HIT Standards Committee work focuses primarily on the standards surrounding certified EHR technology. Further information on the HIT Standards Committee role and recommendations can be found in a future rulemaking document to be provided by ONC for certification of EHR technology (HHS-0151-IFC) and at <http://healthit.hhs.gov>.

Finally, from June 22 to June 26, 2009, the ONC and CMS hosted 21 teleconference listening sessions with rural providers, small practices, small hospitals, CAHs, and urban safety net providers to hear their perspectives and obtain their input on the definition of meaningful use. Because of the

documentation that these types of providers have below average adoption rates of HIT, we solicited comments directly from these communities. Section V. of this proposed rule discusses the current adoption rates of HIT. Over 200 representatives from these target audiences participated on the calls. The vast majority of callers were rural providers, although representatives from vendor organizations or provider associations also participated. One session was held to specifically hear from national organizations representing rural communities and providers. Summaries of these listening sessions are available at <http://healthit.hhs.gov/meaningfuluse>. Both CMS and the ONC have reviewed input from these and additional sources to help inform the definition of meaningful use.

b. Common Definition of Meaningful Use Under Medicare and Medicaid

Under sections 1848(o)(1)(A)(i) and 1886(n)(1) of the Act, as added by sections 4101(a) and 4102(a) of the HITECH Act, respectively, an EP or eligible hospital must be a meaningful EHR user for the relevant EHR reporting period in order to qualify for the incentive payment for a payment year. Sections 1848(o)(2)(A) and 1886(n)(3)(A) of the Act provide that an EP and an eligible hospital shall be considered a meaningful EHR user for an EHR reporting period for a payment year if they meet the following three requirements: (1) Demonstrates use of certified EHR technology in a meaningful manner; (2) demonstrates to the satisfaction of the Secretary that certified EHR technology is connected in a manner that provides for the electronic exchange of health information to improve the quality of health care such as promoting care coordination, in accordance with all laws and standards applicable to the exchange of information; and (3) using its certified EHR technology, submits to the Secretary, in a form and manner specified by the Secretary, information on clinical quality measures and other measures specified by the Secretary. The HITECH Act requires that to receive a Medicaid incentive payment in the initial year of payment, an EP or eligible hospital may demonstrate that they have engaged in efforts to "adopt, implement, or upgrade certified EHR technology." Details, including special timeframes, on how we define and implement "adopt, implement, and upgrade" are proposed in section II.D.7.b.2 of this proposed rule. For subsequent payment years, or the first payment year if an EP or eligible hospital chooses, section

1903(t)(6)(C)(i)(II) of the Act, as added by section 4201(a)(2) of HITECH, prohibits receipt of an incentive payment, unless "the Medicaid provider demonstrates meaningful use of certified EHR technology through a means that is approved by the State and acceptable to the Secretary, and that may be based upon the methodologies applied under section 1848(o) or 1886(n)." (Sections 1848(o) and 1886(n) of the Act refer to the Medicare incentive programs for EPs and eligible hospitals respectively.) Under section 1903(t)(8) of the Act to the maximum extent practicable, we are directed to avoid duplicative requirements from Federal and State governments to demonstrate meaningful use of certified EHR technology. Provisions included at section 1848(o)(1)(D)(iii) of the Act also contain a Congressional mandate to avoid duplicative requirements for meaningful use, to the extent practicable. Finally section 1903(t)(8) of the Act allows the Secretary to deem satisfaction of the requirements for meaningful use of certified EHR technology for a payment year under Medicare to qualify as meaningful use under Medicaid.

We believe that given the strong level of interaction on meaningful use encouraged by the HITECH Act, there would need to be a compelling reason to create separate definitions for Medicare and Medicaid. We have found no such reasons for disparate definitions in our internal or external discussions. To the contrary, stakeholders have expressed strong preferences to link the Medicare and Medicaid EHR incentive programs wherever possible. Hospitals are entitled to participate in both programs, and we are proposing to offer EPs an opportunity to switch between the Medicare and Medicaid EHR incentive programs. Therefore, we propose to create a common definition of meaningful use that would serve as the definition for providers participating in the Medicare FFS and MA EHR incentive program, and the minimum standard for EPs and eligible hospitals participating in the Medicaid EHR incentive program. We clarify that under Medicaid this common definition would be the minimum standard. While we would allow States to add additional objectives to the definition of meaningful use or modify how the existing objectives are measured, the Secretary would not accept any State proposed alternative that does not further promote the use of EHRs and healthcare quality or that would require additional functionality beyond that of certified EHR technology. See section

I.D.7.b.2. of this proposed rule for further details on how a State may propose an alternative.

For hospitals, we propose to exercise the option granted under section 1903(t)(8) of the Act and deem any Medicare provider who is a meaningful EHR user under the Medicare EHR incentive program and is otherwise eligible for the Medicaid incentive payment to be classified as a meaningful EHR user under the Medicaid EHR incentive program. This is applicable only to eligible hospitals, as EPs cannot receive an incentive payment under both Medicare and Medicaid.

We solicit comments as to whether there exist compelling reasons to give the states additional flexibility in creating disparate definitions beyond what is proposed. Also if commenting in favor of such disparate definitions, we ask that interested parties also comment on whether the proposal of deeming meeting Medicare as sufficient for meeting those of Medicaid remains appropriate under the disparate definitions. This is applicable only to hospitals eligible for both the Medicare and Medicaid incentive programs. Furthermore, if a State has CMS-approved additional meaningful use requirements, hospitals deemed as meaningful users by Medicare would not have to meet the State-specific additional meaningful use requirements in order to qualify for the Medicaid incentive payment.

c. Considerations in Defining Meaningful Use

In sections 1848(o)(2)(A) and 1886(n)(3)(A) of the Act, as added by sections 4101(a) and 4102(a) of the HITECH Act, the Congress identifies the broad goal to be accomplished through the definition of meaningful use of certified EHR technology for expanding the use of EHRs. Certified EHR technology used in a meaningful way by providers is one piece of a broader HIT infrastructure needed to reform the health care system and improve health care quality, efficiency, and patient safety. Our goal is for this ultimate vision to drive the definition of meaningful use consistent with applicable provisions of Medicare and Medicaid law.

In defining meaningful use through the creation of criteria, we have balanced competing considerations of proposing a definition that best ensures reform of health care and improved healthcare quality, encourages widespread EHR adoption, promotes innovation, and avoids imposing excessive or unnecessary burdens on healthcare providers, while at the same

time recognizing the short time-frame available under the HITECH Act for providers to begin using certified EHR technology.

Based on public and stakeholder input, we consider a phased approach to be most appropriate. 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, based on anticipated technology and capabilities development. 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 intend to update the criteria of meaningful use through future rulemaking. We refer to the initial meaningful use criteria as "Stage 1." We currently anticipate two additional updates, which we refer to as Stage 2 and Stage 3, respectively. We are considering updating the meaningful use criteria on a biennial basis, with the Stage 2 criteria proposed by the end of 2011 and the Stage 3 definition proposed by the end of 2013. The stages represent a graduated approach to arriving at the ultimate goal. Thus, our goals for "Stage 3" meaningful use criteria represent overarching goals which, we believe, are attainable by the end of the EHR incentive programs. We will continue to evaluate the progression of the meaningful use definition for consistency with legislative intent and new statutory requirements relating to quality measurement. We solicit comments on this proposed pathway of meaningful use.

- Stage 1: The Stage 1 meaningful use criteria focuses on electronically capturing health information in a coded 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); consistent with other provisions of Medicare and Medicaid law, implementing clinical decision support tools to facilitate disease and medication management; and reporting clinical quality measures and public health information.

- Stage 2: Our goals for the Stage 2 meaningful use criteria, consistent with other provisions of Medicare and Medicaid law, expand upon the Stage 1 criteria to 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, such as the electronic transmission of orders entered using computerized provider order entry (CPOE) and the electronic transmission of diagnostic test results (such as blood tests, microbiology, urinalysis, pathology tests, radiology, cardiac imaging, nuclear medicine tests, pulmonary function tests and other such data needed to diagnose and treat disease). Additionally we may consider applying the criteria more broadly to both the inpatient and outpatient hospital settings.

- Stage 3: Our goals for the Stage 3 meaningful use criteria are, consistent with other provisions of Medicare and Medicaid law, to focus on promoting improvements in quality, safety and efficiency, focusing on decision support for national high priority conditions, patient access to self management tools, access to comprehensive patient data and improving population health.

We will continue to evaluate the progression of the meaningful use definition for consistency with legislative instructions and new statutory requirements relating to quality measurement and administrative simplification. We are aware that the appropriate approach raises complex questions and we solicit comments on the proposed approach and alternative possibilities. A different approach might, for example, move aspects of Stage 2 into Stage 3 or vice versa. We seek comments on how best to balance the relevant goals, including promoting adoption of EHRs, avoiding excessive or unnecessary burdens, and improving health care.

As the purpose of these incentives is to encourage the adoption and meaningful use of certified EHR technology, we believe it is desirable to account for whether an EP or eligible hospital is in their first, second, third, fourth, fifth, or sixth payment year when deciding which definition of meaningful use to apply in the beginning years of the program. The HIT Policy Committee in its public meeting on July 16, 2009 also voiced its approval of this approach. However, we do not wish to create an additional burden on EPs or eligible hospitals for becoming a meaningful EHR user before 2015 by creating a higher standard for them relative to an EP or eligible hospital who first becomes a meaningful EHR user in

2015. The following paragraphs describe our intended alignment in the beginning years that brings all EPs and eligible hospitals to the same level of meaningful use by 2015. As we are only proposing criteria for Stage 1 of meaningful use in this notice of proposed rulemaking, Stage 1 will be the criteria for meaningful use for all payment years until updated by future rulemaking. Medicaid EHR incentive program EPs and eligible hospitals have the option to earn their incentive for their first payment year through the adoption, implementation or upgrade of certified EHR technology. Those EPs and eligible hospitals doing so will not have to demonstrate meaningful use in their first payment year. We intend for their progression to be the same as those who demonstrate meaningful use in their first payment year. In other words, the second payment year is the second payment year regardless of how the incentive was earned in the first payment year.

We intend that Medicaid EPs and eligible hospitals who qualify for an incentive payment for adopting, implementing, or upgrading in their first payment year would follow the same meaningful use progression outlined below as if their second payment year was their first payment year. For instance a Medicaid EP who received an incentive for his or her first payment year in 2010 for adopting, implementing, or upgrading would follow the same guidance starting in their second payment year (2011) as a Medicare EP who received an incentive for their first payment year in 2011 for meaningful use of certified EHR technology. Another example would be a Medicaid eligible hospital that received an incentive for its first payment year in 2012 for adopting, implementing, and upgrading would follow the same guidance starting in their second payment year (2013) as a Medicare eligible hospital who received an incentive for their first payment year in 2013 for meaningful use of certified EHR technology.

We propose that EPs and eligible hospitals whose first payment year is 2011 must satisfy the requirements of the Stage 1 criteria of meaningful use in their first and second payment years (2011 and 2012) to receive the incentive payments. We anticipate updating the criteria of meaningful use to Stage 2 in time for the 2013 payment year and therefore anticipate for their third and fourth payment years (2013 and 2014), an EP or eligible hospital whose first payment year is 2011 would have to satisfy the Stage 2 criteria of meaningful use to receive the incentive payments.

We anticipate updating the criteria of meaningful use to Stage 3 in time for the 2015 payment year and therefore anticipate for their fifth payment year (2015), if applicable, an EP or eligible hospital whose first payment year is 2011 would have to satisfy the Stage 3 criteria of meaningful use to receive the incentive payments. For their sixth payment year (2016), if applicable, an EP or eligible hospital whose first payment year is 2011 would have to satisfy the Stage 3 criteria of meaningful use or a subsequent update to the criteria if one is established through rulemaking to receive the incentive payments.

We propose that EPs and eligible hospitals whose first payment year is 2012 must satisfy the Stage 1 criteria of meaningful use in their first and second payment years (2012 and 2013) to receive the incentive payments. We anticipate updating the criteria of meaningful use to Stage 2 in time for the 2013 payment year and anticipate for their third payment year (2014), an EP or eligible hospital whose first payment year is 2012 would have to satisfy the Stage 2 criteria of meaningful use to receive the incentive payments. We anticipate updating the criteria of meaningful use to Stage 3 in time for the 2015 payment year and therefore anticipate for their fourth payment year (2015), if applicable, an EP or eligible hospital whose first payment year is 2012 would have to satisfy the Stage 3 criteria of meaningful use to receive the incentive payments. For their fifth and sixth payment years (2016 and 2017), if applicable, an EP or eligible hospital whose first payment year is 2012 would have to satisfy the Stage 3 criteria of meaningful use or a subsequent update to the criteria if one is established through rulemaking to receive the incentive payments.

We propose that EPs and eligible hospitals whose first payment year is 2013 must satisfy the Stage 1 criteria of meaningful use in their first payment year (2013) to receive the incentive payments. We anticipate updating the criteria of meaningful use to Stage 2 in time for the 2013 payment year and therefore anticipate for their second payment year (2014), an EP or eligible hospital whose first payment year is 2013 would have to satisfy the Stage 2 criteria of meaningful use to receive the incentive payments. We anticipate updating the criteria of meaningful use to Stage 3 in time for the 2015 payment year and therefore anticipate for their third payment year (2015), if applicable, an EP or eligible hospital whose first payment year is 2013 would have to satisfy the Stage 3 criteria of meaningful

use to receive the incentive payments. For their fourth, fifth, and sixth payment year (2016, 2017 and 2018), if applicable, an EP or eligible hospital whose first payment year is 2013 would have to satisfy the Stage 3 criteria of meaningful use or a subsequent update to the criteria if one is established through rulemaking to receive the incentive payments.

We propose that EPs and eligible hospitals whose first payment year is 2014 must satisfy the Stage 1 criteria of meaningful use in their first payment year (2014) to receive the incentive payments. We anticipate updating the criteria of meaningful use to Stage 3 in time for the 2015 payment year and therefore anticipate for their second payment year (2015), if applicable, an EP or eligible hospital whose first payment year is 2014 would have to satisfy the Stage 3 criteria of meaningful use to receive the incentive payments. For their third, fourth, fifth and sixth payment year (2016, 2017, 2018, and 2019), if applicable, an EP or eligible hospital whose first payment year is 2014 would have to satisfy the Stage 3 criteria of meaningful use or a subsequent update to the criteria if one is established through rulemaking to receive the incentive payments.

We anticipate updating the criteria of meaningful use to Stage 3 in time for the 2015 payment year and therefore anticipate for all their payment years, an EP or eligible hospital whose first payment year is 2015 would have to satisfy the Stage 3 criteria of meaningful use for 2015. For all subsequent payment years, if applicable, an EP or eligible hospital whose first payment year is 2015 would have to satisfy the Stage 3 criteria of meaningful use or a subsequent update to the criteria if one is established through rulemaking to receive the incentive payments.

In addition to the equitable concerns discussed earlier in the transition from incentive payments to payment adjustments, the primary reasoning for developing different stages of meaningful use is the current lack of HIT infrastructure and penetration of qualified EHRs necessary to support the ambitious goals of the Stage 3 criteria of meaningful use. Given the anticipated maturity of HIT infrastructure inherent in the strengthening criteria and the increased adoption of certified EHR technology predicted in section V. of this proposed rule, these barriers to meeting the Stage 3 criteria of meaningful use will be removed.

Table 1 outlines our proposal to apply the respective criteria of meaningful use for each payment year (1st, 2nd, 3rd, etc.) for EPs and eligible hospitals that

become meaningful EHR users before 2015. Please note that nothing in this discussion limits us to proposed

changes to meaningful use beyond Stage 3 through future rulemaking.

TABLE 1—STAGE OF MEANINGFUL USE CRITERIA BY PAYMENT YEAR

First payment year	Payment year				
	2011	2012	2013	2014	2015 +**
2011	Stage 1	Stage 1	Stage 2	Stage 2	Stage 3.
2012	Stage 1	Stage 1	Stage 2	Stage 3.
2013	Stage 1	Stage 2	Stage 3.
2014	Stage 1	Stage 3.
2015+*	Stage 3.

* Avoids payment adjustments only for EPs in the Medicare EHR Incentive Program.

** Stage 3 criteria of meaningful use or a subsequent update to the criteria if one is established through rulemaking.

Please note that the number of payment years available and the last payment year that can be the first payment year for an EP or eligible hospital varies between the EHR incentive programs. The applicable payment years for each program are discussed in section II.B. of this proposed rule for the Medicare FFS EHR incentive program, in section II.D. for the MA EHR incentive program, and in section II.E. for the Medicaid EHR incentive program.

The stages of criteria of meaningful use and how they are demonstrated are described further in this proposed rule and will be updated in subsequent proposed rules to reflect advances in HIT products and infrastructure. This could include updates to the Stage 1 criteria in future rulemaking.

We invite comments on our alignment between payment year and the criteria of meaningful use particularly in regard to the need to create alignment across all EPs and eligible hospitals in all EHR incentive programs in 2015.

d. Stage 1 Criteria for Meaningful Use

To qualify as a meaningful EHR user for 2011, we propose that an EP or eligible hospital must demonstrate that they meet all of the objectives and their associated measures as set forth in § 495.6. Except as otherwise indicated, each objective must be satisfied by an individual EP as determined by unique National Provider Identifiers (NPIs) and an individual hospital as determined by unique CMS certification numbers (CCN). Below we describe each objective and its associated measures in detail. While we welcome comments on all aspects of the Stage 1 criteria of meaningful use, we specifically encourage comments on the following considerations.

While we believe that requiring satisfaction of all objectives is appropriate for the majority of providers, we are concerned that certain

providers may have difficulty meeting one or more of the proposed objectives. We solicit comments on whether this may be the case, and invite commenters to identify the objectives and associated measures that may prove out of reach for certain provider types or specialties, and to suggest specific objective criteria we could use to determine whether an objective and associated measure is appropriate for different provider types or specialists.

In discussing the objectives that constitute the stage 1 criteria of meaningful use, we adopted a structure derived from recommendations of the HIT Policy Committee of grouping the objectives under care goals, which are in turn grouped under health outcomes policy priorities. We believe this structural grouping provides context to the individual objectives; however, the grouping is not itself an aspect of meaningful use. The criteria for meaningful use are based on the objectives and their associated measures. CMS and ONC have carefully reviewed the objectives and measures proposed by the HIT Policy Committee. We found many objectives to be well suited to meaningful use, while others we found to require modification or clarification. In our discussion we will focus on those areas where our proposal is a modification of the recommendation of the HIT Policy Committee. For those areas where we elected not to propose a modification to the recommendation of the HIT Policy Committee, we note that there already has been extensive public debate and explanation of these recommendations, which can be accessed at <http://healthit.hhs.gov/meaningfuluse>. Even if we do not propose to modify a specific recommendation of the HIT Policy Committee, we nevertheless welcome comment on whether to do so in the final rule.

(1) Objectives

The first health outcomes policy priority specified by the HIT Policy Committee is improving quality, safety, efficiency and reducing health disparities. The HIT Policy Committee identified the following care goals to address this priority:

- Provide access to comprehensive patient health data for patient's healthcare team.
- Use evidence-based order sets and computerized provider order entry (CPOE).
- Apply clinical decision support at the point of care.
- Generate lists of patients who need care and use them to reach out to those patients.
- Report information for quality improvement and public reporting.

With respect to this last care goal, the HIT Policy Committee proposed a goal of "Report to patient registries for quality improvement, public reporting, etc." We propose to modify this care goal because we believe that patient registries are too narrow a reporting requirement to accomplish the goals of quality improvement and public reporting. We note that the HIT Policy Committee's recommended objectives include the reporting of quality measures to CMS. We do not believe that CMS would normally be considered a "patient registry." We also removed the phrase "etc." We believe that the level of ambiguity created by "etc." is not appropriate for Federal regulations.

For EPs, we propose the following objectives in the Stage 1 criteria of meaningful use to further the care goal of improving quality, safety, efficiency and reducing health disparities.

- Use CPOE. We believe that the term "CPOE" requires additional clarification. We propose 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 also documented or captured in a digital, structured, and computable format for use in improving safety and organization. For Stage 1 criteria, we propose that it will not include the electronic transmittal of that order to the pharmacy, laboratory, or diagnostic imaging center. We encourage comments on whether additional specificity is required on the types of orders encompassed within CPOE.

- Implement drug-drug, drug-allergy, drug-formulary checks.
- Maintain an up-to-date problem list of current and active diagnoses based on ICD-9-CM or SNOMED CT®.

We believe the term “problem list” requires additional clarification. We describe a “problem list” as a list of current and active diagnoses as well as past diagnoses relevant to the current care of the patient.

- Generate and transmit permissible prescriptions electronically (eRx).

The concept of only permissible prescriptions refers to the current restrictions established by the Department of Justice on electronic prescribing for controlled substances. (The restrictions can be found at <http://www.deadiversion.usdoj.gov/schedules/schedules.htm>.)

- Maintain active medication list.
- Maintain active medication allergy list.
- Record the following demographics: Preferred language, insurance type, gender, race and ethnicity, and date of birth.

We note that race and ethnicity codes should follow current federal standards published by the Office of Management and Budget (http://www.whitehouse.gov/omb/inforeg_statpolicy/#dr).

- We do not propose to include the objective “Record Advance directives.” The HIT Policy Committee recommended that EPs “record advance directives.” It is unclear whether by this terminology they meant that the contents of the advance directive be recorded or merely the fact that a patient has an advance directive be noted. Depending on the interpretation, this objective could interfere with current State law which varies significantly from State to State in this matter. We also believe that this objective is only relevant to a limited and undefined patient population when compared to the patient populations to which other objectives listed here apply. The limits could be based on age, health

status, whether a chronic condition is present, to patients scheduled for certain types of procedures or a host of other factors. Similarly, many EPs would not record this information under current standards of practice. Dentists, pediatricians, optometrists, chiropractors, dermatologists, and radiologists are just a few examples of EPs who would only in rare circumstances require information about a patient’s advance directive. For these reasons, we do not propose to include “Record advance directives” as an objective of the Stage 1 criteria of meaningful use for EPs.

- Record and chart changes in the following vital signs: Height, weight and blood pressure and calculate and display body mass index (BMI) for ages 2 and over; plot and display growth charts for children 2–20 years, including BMI.

This is a modification to the HIT Policy Committee recommendation to require eligible professionals to record vital signs: Height, weight, blood pressure and calculate BMI. We added “plot and display growth charts for children 2–20 years, including BMI” to the objective recommended by the HIT Policy Committee, as BMI itself does not provide adequate information for children. Trends in height, weight, and BMI among children must be interpreted and understood in the context of expected parameters of children of the same age and sex to determine whether the child is growing appropriately. For example, a BMI of 18 is normal for a 12-year-old boy, and a marker of obesity for a 5-year-old (<http://www.cdc.gov/growthcharts/data/set1clinical/cj411023.pdf>).

- Record smoking status for patients 13 years old or older.

The HIT Policy Committee recommended the objective of recording smoking status for patients. We propose to add “for patients 13 years old or older,” as we do not believe this objective is applicable to patients of all ages and there is not consensus in the health care community as to what the appropriate cut off age may be. We encourage comments on whether this age limit should be lowered or raised.

- Incorporate clinical lab-test results into EHR as structured data. Structured data are data that have specified data type and response categories within an electronic record or file.

- Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, research, and outreach.

- Report ambulatory quality measures to CMS (or, for EPs seeking the

Medicaid incentive payment, the States). The HIT Policy Committee did not include “or the States” in its recommended objective. We propose to add the option to report directly to the States for EPs participating in the Medicaid EHR incentive program. Additional discussion of this objective can be found in section II.A.3 of this proposed rule.

- Send reminders to patients per patient preference for preventive/follow-up care. Patient preference refers to the patient’s choice of delivery method between internet based delivery or delivery not requiring internet access.

- Implement five clinical decision support rules relevant to specialty or high clinical priority, including for diagnostic test ordering, along with the ability to track compliance with those rules.

This is a modification to the HIT Policy Committee recommendation to require EPs to implement one clinical decision support rule relevant to specialty or high clinical priority. We made this change to align with and support eligible professionals in reporting their clinical quality measures proposed in section II.A.3. of this proposed rule. We anticipate that EPs will report on at least five clinical quality measures.

We propose to describe clinical decision support as health information technology functionality that builds upon the foundation of an EHR to provide persons involved in care processes with general and person-specific information, intelligently filtered and organized, at appropriate times, to enhance health and health care.

- We do not propose to include the objective “Document a progress note for each encounter”. Documentation of progress notes is a medical-legal requirement and a component of basic EHR functionality, and is not directly related to advanced processes of care or improvements in quality, safety, or efficiency.

Finally, the HIT Policy Committee further recommended the following two objectives related to administrative simplification. Consistent with that recommendation—and consistent with any forthcoming statutory requirements regarding administrative simplifications—we propose the following objectives, with slight modification.

- Check insurance eligibility electronically from public and private payers. Deleted “where possible” from the HIT Policy Committee recommendation. The checking for

eligibility electronically is already a HIPAA Standard Exchange.

- Submit claims electronically to public and private payers.

For eligible hospitals, we propose the following objectives in the stage 1 criteria of meaningful use to further these care goals:

- Use CPOE for orders (any type) directly entered by the authorizing provider (for example, MD, DO, RN, PA, NP).

We believe that the term “CPOE” requires additional clarification. We propose 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 also documented or captured in a digital, structured, and computable format for use in improving safety and organization. It does not include the electronic transmittal of that order to the pharmacy, laboratory, or diagnostic imaging center in 2011 or 2012. CPOE is the same as defined above for EPs. We welcome comment on whether use of CPOE varies between hospitals and EPs in ways that should be addressed.

- Implement drug-drug, drug-allergy, drug-formulary checks.
- Maintain an up-to-date problem list of current and active diagnoses based on ICD-9-CM or SNOMED CT®.

We believe the term “problem list” requires additional clarification. We describe a “problem list” as a list of current and active diagnoses, as well as past diagnoses relevant to the current care of the patient.

- Maintain active medication list.
- Maintain active medication allergy list.
- Record the following demographics: preferred language, insurance type, gender, race and ethnicity, date of birth, and date and cause of death in the event of mortality.

We are interested in public comments on how States and hospitals could work together to facilitate linkage between the EHR and the full birth and death certificate information that States currently require hospitals to collect. We note that race and ethnicity codes should follow current federal standards published by the Office of Management and Budget (http://www.whitehouse.gov/omb/inforeg_statpolicy/#dr).

- We do not propose to include the objective “Record Advance directives.” The HIT Policy Committee recommended that eligible hospitals

“record advance directives.” It is unclear whether by this terminology they meant that the contents of the advance directive be recorded or merely the fact that a patient has an advance directive be noted. Depending on the interpretation, this objective could interfere with current State law which varies significantly from state to state in this matter. We also believe that this objective is only relevant to a limited and undefined patient population when compared to the patient populations to which other objectives listed here apply. The limits could be based on age, health status, whether a chronic condition is present, to patients scheduled for certain types of procedures or a host of other factors. For these reasons, we do not propose to include “Record advance directives” as an objective of the Stage 1 criteria of meaningful use for eligible hospitals.

- Record the following vital signs: height, weight and blood pressure and calculate and display body mass index (BMI) for patients 2 and over; plot and display growth charts for children 2–20 years, including BMI.

We added “plot and display growth charts for children 2–20 years, including BMI” to the objective recommended by the HIT Policy Committee, as BMI itself does not provide adequate information for children. Trends in height, weight, and BMI among children must be interpreted and understood in the context of expected parameters of children of the same age and sex to determine whether the child is growing appropriately. For example, a BMI of 18 is normal for a 12-year-old boy, and a marker of obesity for a 5-year-old (ref. <http://www.cdc.gov/growthcharts/data/set1clinical/cj41023.pdf>).

- Record smoking status for patients 13 years old or older.

We added “for patients 13 years old or older” as this objective is not applicable to patients of all ages. The discussion as to why we chose 13 can be found under the EP objective for “Record smoking status”.

- Incorporate clinical lab-test results into EHR as structured data. Structured data are data that have specified data type and response categories within a record or file.
- Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, and outreach.

The HIT Policy Committee did not recommend the phrase “to use for quality improvement, reduction of disparities, and outreach” for eligible hospitals as they did for EPs. We believe this aspect of the objective is just as

relevant to eligible hospitals as EPs and therefore includes it for both. We invite comments as to why this phrase may not be applicable to eligible hospitals.

- Report ambulatory quality measures to CMS (or, for eligible hospitals seeking the Medicaid incentive payment, the States). The HIT Policy Committee did not include “or the States” in their recommended objective. We propose to add the option to report directly to the States for Medicaid eligible hospitals participating in the Medicaid EHR incentive program. Additional discussion can be found in section II.A.3. of this proposed rule.

- Implement five clinical decision support rules relevant to specialty or high clinical priority, including for diagnostic test ordering, along with the ability to track compliance with those rules.

This is a modification to the HIT Policy Committee recommendation to require eligible professionals to implement one clinical decision support rule relevant to specialty or high clinical priority. We made this change to align with and support eligible professionals in reporting their clinical quality measures proposed in section II.A.3. of this proposed rule. We anticipate that most EPs will report on at least five clinical quality measures from section II.A.3 of this proposed rule and eligible hospitals will all report on at least five.

We believe greater clarification is required around the term clinical decision support. We propose to describe clinical decision support as health information technology functionality that builds upon the foundation of an EHR to provide persons involved in care processes with general and person-specific information, intelligently filtered and organized, at appropriate times, to enhance health and health care.

Finally, the HIT Policy Committee further recommended the following two objectives related to administrative simplification. Consistent with that recommendation—and consistent with any forthcoming statutory requirements regarding administrative simplifications—we propose the following objectives, with slight modification.

- Check insurance eligibility electronically from public and private payers. Deleted “where possible” from the HIT Policy Committee recommendation. The checking for eligibility electronically is already a HIPAA Standard Exchange.
- Submit claims electronically to public and private payers.

The second health outcomes policy priority identified by the HIT Policy

Committee is to engage patients and families in their healthcare. The following care goal for meaningful use addresses this priority:

- Provide patients and families with timely access to data, knowledge, and tools to make informed decisions and to manage their health. We do not propose to preempt any existing Federal or State law regarding the disclosure of information to minors, their parents, or their guardians in setting the requirements for meaningful use. For this reason when it comes to information provided to the family, we let existing Federal and State laws dictate what is appropriate for disclosure to the patient or the family. For purposes of all objectives of the Stage 1 criteria of meaningful use involving the disclosure of information to a patient, a disclosure made to a family member or a patient's guardian consistent with Federal and State law may substitute for a disclosure to the patient.

For EPs, we propose the following objectives in the stage 1 criteria of meaningful use to further this care goal:

- Provide patients with an electronic copy of their health information (including diagnostics test results, problem list, medication lists, allergies) upon request.

Consistent with the HIT Policy Committee's recommendations, we propose the following additional clarification of this objective. Electronic copies may be provided through a number of secure electronic methods (for example, personal health record (PHR), patient portal, CD, USB drive).

- Provide patients with timely electronic access to their health information (including lab results, problem list, medication lists, allergies) within 96 hours of the information being available to the EP.

Also, consistent with the HIT Policy Committee recommendations, we propose the following additional clarification of this objective. Electronic access may be provided by a number of secure electronic methods (for example, PHR, patient portal, CD, USB drive). Timely is defined as within 96 hours of the information being available to the EP either through the receipt of final lab results or a patient interaction that updates the EP's knowledge of the patient's health. We judge 96 hours to be a reasonable amount of time to ensure that certified EHR technology is up to date. We welcome comment on if a shorter or longer time is advantageous.

- We do not propose to include the objective "Provide access to patient-specific education resources upon

request." Providing patients with information and education that is relevant to their condition, actionable, culturally competent, and of the appropriate health literacy level is a critical component of patient engagement and empowerment. Unfortunately, there is currently a paucity of knowledge resources that are integrated within EHRs, that are widely available, and that meet these criteria, particularly in multiple languages. We intend to work with the policy committee, the National Library of Medicine (provider of Medline Plus), and experts in this area to ensure the feasibility of this measure in the future.

- Provide clinical summaries for patients for each office visit.

Changed from encounter to office visit. The HIT Policy Committee recommended the objective "Provide clinical summaries for patients for each encounter." We believe this objective requires further clarification in order to make the distinction that it is not meant to apply to alternative encounters such as telephone or Web visits. As a result, we propose to revise this objective to "Provide clinical summaries for patients for each office visit."

For eligible hospitals, we propose the following objectives in the stage 1 criteria of meaningful use to further this care goal:

- Provide patients with an electronic copy of their health information (including diagnostic test results, problem list, medication lists, allergies, discharge summary, procedures), upon request. Consistent with the HIT Policy Committee's recommendations, we propose the following additional clarification of this objective. Electronic copies may be provided through a number of secure electronic methods (for example, Personal Health Record (PHR), patient portal, CD, USB drive).

- Provide patients with an electronic copy of their discharge instructions and procedures at time of discharge, upon request.

Also, consistent with the HIT Policy Committee recommendations, we propose the following additional clarification of this objective. Electronic access may be provided by a number of secure electronic methods (for example, PHR, patient portal, CD, USB drive).

- We do not propose to include the objective "Provide access to patient-specific education resources upon request." Providing patients with information and education that is relevant to their condition, actionable, culturally competent, and of the appropriate health literacy level is a critical component of patient

engagement and empowerment. Unfortunately, there is currently a paucity of knowledge resources that are integrated within EHRs, that are widely available, and that meet these criteria, particularly in multiple languages. We intend to work with the policy committee, the National Library of Medicine (provider of Medline Plus), and experts in this area to ensure the feasibility of this measure in the future.

The third health outcomes policy priority identified by the HIT Policy Committee is to improve care coordination. The HIT Policy Committee recommended the following care goals to address this priority:

- Exchange meaningful clinical information among professional health care team.

For EPs and eligible hospitals, we propose the following objectives in the stage 1 criteria of meaningful use to further this care goal:

- Capability to exchange key clinical information (for example, problem list, medication list, allergies, and diagnostic test results), among providers of care and patient authorized entities electronically.

By "diagnostic test results" we mean all data needed to diagnose and treat disease, such as blood tests, microbiology, urinalysis, pathology tests, radiology, cardiac imaging, nuclear medicine tests, and pulmonary function tests. Where available in structured electronic format (for example, drug and clinical lab data), we expect that this information would be exchanged in electronic format. However, where the information is available only in unstructured electronic formats (for example, free text and scanned images), we would allow the exchange of unstructured information. Patient authorized entities could include any individual or organization to which the patient has granted access to their clinical information. Examples would include an insurance company that covers the patient or a personal health record vendor identified by the patient.

- Perform medication reconciliation at relevant encounters and each transition of care.

We believe greater clarification is needed around the term "medication reconciliation". Public input received by the NCVHS Executive Subcommittee and the HIT Policy Committee and our prior experiences indicate confusion in the healthcare industry as to what constitutes medication reconciliation. We propose to describe 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. Also we would clarify transition of care as transfer of a patient from one clinical setting (inpatient, outpatient, physician office, home health, rehab, long-term care facility, etc.) to another or from one EP or eligible hospital (as defined by CCN) to another. A relevant encounter would be any encounter that the EP or eligible hospital judges performs a medication reconciliation due to new medication or long gaps in time between patient encounters or other reasons determined by the EP or eligible hospital. We encourage comments on whether our descriptions of “transition of care” and “relevant encounter” are sufficiently clear and medically relevant.

- Provide summary care record for each transition of care or referral.

This objective was not explicitly included in the HIT Policy Committee’s recommended objectives. However, they did include a measure for the “percent of transitions in care for which summary care record is shared. We believe that in order for a measure to be relevant it must correspond to an objective in the definition of meaningful use. Therefore, we propose to add this objective in order to be able to include the recommended measure. Furthermore, we add referrals because the sharing of the patient care summary from one provider to another communicates important information that the patient may not have been able to provide, and can significantly improve the quality and safety of referral care, and reduce unnecessary and redundant testing.

The fourth health outcomes policy priority identified by the HIT Policy Committee is improving population and public health. The HIT Policy Committee identified the following care goal to address this priority:

- The patient’s health care team communicates with public health agencies. The goal as recommended by the HIT Policy Committee is “communicate with public health agencies.” We found this goal to be somewhat ambiguous, as it does not specify who must communicate with public health agencies. We propose to specify “the patient’s health care team” as who would communicate with public health agencies.

For EPs, we propose the following objectives in the stage 1 criteria of meaningful use to further this care goal:

- Capability to submit electronic data to immunization registries and actual

submission where possible and accepted.

- Capability to provide electronic syndromic surveillance data to public health agencies and actual transmission according to applicable law and practice.

For eligible hospitals, we propose the following objectives in the stage 1 criteria of meaningful use to further this care goal:

- Capability to submit electronic data to immunization registries and actual submission where required and accepted.

- Capability to provide electronic submission of reportable (as required by state or local law) lab results to public health agencies and actual submission where it can be received.

- Capability to provide electronic syndromic surveillance data to public health agencies and actual transmission according to applicable law and practice.

The fifth health outcomes policy priority is to ensure adequate privacy and security protections for personal health information. The following care goals for meaningful use address this priority:

- Ensure privacy and security protections for confidential information through operating policies, procedures, and technologies and compliance with applicable law.

- Provide transparency of data sharing to patient.

For EPs and eligible hospitals, we propose the following objective in the stage 1 criteria of meaningful use to further these care goals:

- Protect electronic health information created or maintained by the certified EHR technology through the implementation of appropriate technical capabilities.

This objective is different from the two objectives recommended by the HIT Policy Committee. Those objectives were “Compliance with HIPAA Privacy and Security Rules” and “Compliance with fair data sharing practices set forth in the Nationwide Privacy and Security Framework”. While we presume that the HIT Policy Committee is referring to the certified EHR technology and its use being in compliance with the HIPAA Privacy and Security Rules, it is not explicit. Compliance with HIPAA privacy and security rules is required for all covered entities, regardless of whether they participate in the EHR incentive programs or not. Furthermore, compliance constitutes a wide range of activities, procedures, and infrastructure. We propose to rephrase the objective to ensure that meaningful

use of the certified EHR technology supports compliance with the HIPAA Privacy and Security Rules and compliance with fair sharing data practices outlined in the Nationwide Privacy and Security Framework (http://healthit.hhs.gov/portal/server.pt/gateway/PTARGS_0_10731_848088_0_0_18/NationwidePS_Framework-5.pdf), but do not believe meaningful use of certified EHR technology is the appropriate regulatory tool to ensure such compliance with the HIPAA Privacy and Security Rules.

(2) Health IT Functionality Measures

In order for an EP or an eligible hospital to demonstrate that it meets these proposed objectives, we believe a measure is necessary for each objective. To provide structure to these measures, we group the measures into two categories: Health IT functionality measures and clinical quality measures. The health IT functionality measures are discussed in this section, while the clinical quality measures are discussed in section II.A.3 of this proposed rule.

Without a measure for each objective, we believe that the definition of meaningful use becomes too ambiguous to fulfill its purpose. The use of measures also creates the flexibility to account for realities of current HIT products and infrastructure and the ability to account for future advances. The HIT Policy Committee did recommend some measures; however, they did not explicitly link each measure to an objective. Therefore, the proposed measures set forth below are a significant departure from the recommendation of the HIT Policy Committee.

For each of these measures utilizing a percentage and the reporting of clinical quality measures, we propose at § 495.10 that EPs and eligible hospitals submit numerator and denominator information to CMS. We invite comment on our burden estimates associated with reporting these measures (see section III. of this proposed rule).

EP Objective: Use CPOE.

EP Measure: CPOE is used for at least 80 percent of all orders.

CPOE is a capability included in the certification criteria for certified EHR technology (to be defined by the ONC in its upcoming interim final rule). We believe it is important to ensure that this capability is continuously utilized. Therefore, we believe in order to meet this objective it is not sufficient to demonstrate use of this capability once, but rather, an EP must utilize this capability as part of his or her daily work process.

We consider two methods of for measuring use of the CPOE functionality: the percentage of orders entered using CPOE or a count of orders entered using CPOE. To illustrate the difference, an example of measuring percentage use of the CPOE functionality would be 80 percent of all of an EP's orders were entered using the CPOE functionality of certified EHR technology during the EHR reporting period. An example of counting orders using the CPOE functionality would be requiring that the EP entered at least 100 orders using CPOE during the EHR reporting period. A count of orders entered using CPOE would be easier to document than a percentage of orders, as an EP would only have to count the number of times he or she entered an order using CPOE, as opposed to tabulating both when he or she did so and when he or she failed to do so. However, a count does not enable variations between EPs to be accounted for. For instance, a count-based measurement would not take into consideration differences in patient volume among EPs, which may be a concern to those EPs with a low patient volume. A percentage-based measurement would account for variations in volume and would allow for a more revealing measurement of an EP's individual performance in meeting the objective. Therefore, we are proposing that an EP's successful completion of this objective be based on a percentage.

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

- The numerator.
- The denominator.
- The required percentage for demonstrating successful attainment of an objective.

The numerator for this objective is orders issued by the EP entered using the CPOE functionality of certified EHR technology during the EHR reporting period. The denominator for this objective is all orders issued by the EP during the EHR reporting period. These are orders issued by an EP for both their Medicare/Medicaid population and all other patients. We believe it is unlikely that an EP would use one record keeping system for one patient population and another system for another patient population at one location. Requiring reporting differences based on payers would actually increase the burden of meeting meaningful use. We are concerned about the application of this denominator for EPs who see patients in multiple practices or multiple locations. If an EP does not have certified EHR technology available

at each location/practice where they see patients it could become impossible to reach the thresholds set for measuring the objectives. We do not seek to exclude EPs who meaningfully use certified EHR technology when it is available because they also provide care in another practice where certified EHR technology is not available. Therefore we are proposing all measures be limited to actions taken at practices/locations equipped with certified EHR technology. A practice is equipped if certified EHR technology is available at the beginning of the EHR reporting period for a given location. Equipped does not mean the certified EHR technology is functioning on any given day in the EHR reporting period. Allowances for downtime and other technical issues with certified EHR technology are made in the establishment of the measure thresholds. We are concerned that seeing a patient without certified EHR technology available does not advance the health care policy priorities of the definition of meaningful use. We are also concerned about possible inequality between EPs receiving the same incentive, but using certified EHR technology for different proportions of their patient population. We believe that an EP would have the greatest control of whether certified EHR technology is available in the practice in which they see the greatest proportion of their patients. We are proposing that to be a meaningful EHR user an EP must have 50 percent or more of their patient encounters during the EHR reporting period at a practice/location or practices/locations equipped with certified EHR technology. An EP for who does not conduct 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. While control is less assured in this situation, CMS still needs to advance the health care priorities of the definition of meaningful use and provide some level of equity. We invite comments as to whether this denominator is feasible to obtain for EPs, whether this exclusion (the denominator for patients seen when certified EHR technology is not available) is appropriate, whether a minimum threshold is necessary and whether 50 percent is an appropriate threshold. We note that in evaluating the 50 percent threshold, our proposal is to review all locations/organizations at which an EP practices. So, for example, if the EP practices at both an FQHC and within his or her individual

practice, we would include in our review both of these locations.

As this objective relies solely on a capability included as part of certified EHR technology and is not, for purposes of Stage 1 criteria, reliant on the electronic exchange of information, we believe it would be appropriate to set a high percentage threshold. We therefore propose to set the percentage required for successful demonstration at 80 percent. Though full compliance (that is, 100 percent) is the ultimate goal, 80 percent seemed an appropriate standard for Stage 1 meaningful use as it creates a high standard, while still allowing room for technical hindrances and other barriers to reaching full compliance.

For other objectives that are reliant on the electronic exchange of information, we are cognizant that in most areas of the country, the infrastructure necessary to support such exchange is not yet currently available. We anticipate raising the threshold for these objectives in future definitions of meaningful use as the capabilities of HIT infrastructure increases. The intent and policy goal with raising this threshold is to ensure that meaningful use encourages patient-centric, interoperable health information exchange across provider organizations regardless of provider's business affiliation or EHR platform.

Eligible Hospital Objective: Use of CPOE for orders (any type) directly entered by authorizing provider (for example, MD, DO, RN, PA, NP).

Eligible Hospital Measure: CPOE is used for at least 10 percent of all orders.

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

- The numerator.
- The denominator.
- The required percentage for demonstrating successful attainment of an objective.

The numerator for this objective is orders entered in an inpatient facility/department that falls under the eligible hospital's CCN and by an authorized provider using CPOE functionality of certified EHR technology during the EHR reporting period. Inpatient facility/department is defined by the place of service code 21. Further discussion about POS 21 is available at section II.A.6. of this proposed rule and at <http://www.cms.hhs.gov/PlaceofServiceCodes/>. The denominator for this objective is all orders entered in an inpatient facility/department that falls under the eligible hospital's CCN and issued by the authorized providers in the hospital during the EHR reporting period. These are orders are those issued are for both their Medicare/Medicaid population and all other

patients. The rationale for the establishment of this measure is identical to that of the EP, except in the establishment of the threshold percentage. In considering CPOE, the HIT Policy Committee did specify this lower percentage (10 percent) for eligible hospitals. Public input described previously in this proposed rule indicated that CPOE is traditionally one of the last capabilities implemented at hospitals. Also, many hospitals choose to implement one department at a time. Detailed comments can be found at <http://healthit.hhs.gov/meaningfuluse>. For these reasons the HIT Policy Committee recommended this lower threshold. We agree with the lower threshold for the same reasons.

EP/Eligible Hospital Objective:

Implement drug-drug, drug-allergy, drug-formulary checks.

EP/Eligible Hospital Measure: The EP/eligible hospital has enabled this functionality.

The capability of conducting automated drug-drug, drug-allergy, and drug-formulary checks is included in the certification criteria for certified EHR technology (to be determined by ONC in its upcoming interim final rule). This automated check provides information to advise the EP or eligible hospital's decisions in prescribing drugs to a patient. The only action taken by the EP or eligible hospital is to consider this information. Many current EHR technologies have the option to disable these checks and the certification process does not require the removal of this option. Therefore, in order to meet this objective, an EP or eligible hospital would be required to enable this functionality. While this does not ensure that an EP or an eligible hospital is considering the information provided, it does ensure that the information is available.

EP/Eligible Hospital Objective: Maintain an up-to-date problem list of current and active diagnoses based on ICD-9-CM or SNOMED CT®.

EP/Eligible Hospital Measure: At least 80 percent of all unique patients seen by the EP or admitted to the eligible hospital have at least one entry or an indication of none recorded as structured data.

The capability to maintain an up-to-date problem list of current and active diagnoses based on ICD-9-CM or SNOMED CT® is included in the certification criteria for certified EHR technology (to be defined by ONC in its upcoming interim final rule). Meaningful use seeks to ensure that those capabilities are utilized. Therefore, we believe in order to meet this objective it is not sufficient to

demonstrate this capability once, but rather to comply with the objective, an EP or an eligible hospital must utilize this capability as part of the daily work process.

As discussed under CPOE, we will use a percentage. To calculate the percentage, CMS and ONC have worked together to define the following for this objective:

- The numerator.
- The denominator.
- The required percentage for demonstrating successful attainment of an objective.

The numerator for this objective is the number of unique patients seen by an EP or admitted to an inpatient facility/department (POS 21) that falls under the eligible hospital's CCN during the EHR reporting period that have at least one ICD-9-CM or SNOMED CT® -coded entry or an indication of none in the problem list. A unique patient means that even if a patient is seen multiple times during the EHR reporting period they are only counted once. The reason we propose to base the measure on unique patients as opposed to every patient encounter, is that a problem list would not necessarily have to be updated at every visit. The denominator for this objective is the number of unique patients seen by the EP or admitted to an inpatient facility/department (POS 21) that falls under the eligible hospital's CCN during the EHR reporting period. As this objective relies solely on a capability included as part of certified EHR technology and is not reliant on the electronic exchange of information, we propose to set the percentage required for successful demonstration at 80 percent. The reasoning for this is the same as under CPOE for EPs. Though full compliance (that is, 100 percent) is the ultimate goal, 80 percent seemed an appropriate standard for Stage 1 meaningful use as it creates a high standard, while still allowing room for technical hindrances and other barriers to reaching full compliance.

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

EP Measure: At least 75 percent of all permissible prescriptions written by the EP are transmitted electronically using certified EHR technology.

The capability to generate and transmit permissible prescriptions electronically is included in the certification criteria for certified EHR technology (to be defined by ONC in its upcoming interim final rule). Meaningful use seeks to ensure that those capabilities are utilized. Therefore, we believe in order to meet

this objective it is not sufficient to demonstrate this capability once, but rather to comply with the objective, an EP must utilize this capability as part of the daily work process.

As discussed under CPOE, we will use a percentage. To calculate the percentage, CMS and ONC have worked together to define the following for this objective:

- The numerator.
- The denominator.
- The required percentage for demonstrating successful attainment of an objective.

The numerator for this objective is the number of prescriptions for other than controlled substances generated and transmitted electronically during the EHR reporting period. The denominator for this objective is the number of prescriptions written for other than controlled substances during the EHR reporting period. While this measure does rely on the electronic exchange of information based on the public input previously discussed and our own experiences with e-Rx programs, we believe this is the most robust electronic exchange currently occurring and propose 75 percent as an achievable threshold for the Stage 1 criteria of meaningful use. Though full compliance (that is, 100 percent) is the ultimate goal, 75 percent seemed an appropriate standard for Stage 1 meaningful use as it creates a high standard, while still allowing room for technical hindrances and other barriers to reaching full compliance.

EP/Eligible Hospital Objective:

Maintain active medication list.

EP/Eligible Hospital Measure: At least 80 percent of all unique patients seen by the EP or admitted by the eligible hospital have at least one entry (or an indication of "none" if the patient is not currently prescribed any medication) recorded as structured data.

The capability to maintain an active medication list is included in the certification standards for certified EHR technology (to be defined by ONC in its upcoming interim final rule). Meaningful use seeks to ensure that those capabilities are utilized. Therefore, we believe in order to meet this objective it is not sufficient to demonstrate this capability once, but rather to comply with the objective, an EP or eligible hospital must utilize this capability as part of the daily work process.

As discussed under CPOE, we will use a percentage. To calculate the percentage, CMS and ONC have worked together to define the following for this objective:

- The numerator.

- The denominator.
- The required percentage for demonstrating successful attainment of an objective.

The numerator for this objective is the number of unique patients seen by the EP or admitted to an inpatient facility/department (POS 21) that falls under the eligible hospital's CCN during the EHR reporting period who have at least one entry (or an indication of "none" if the patient is not currently prescribed any medication) recorded as structured data in their medication list. A unique patient is discussed under the objective of maintaining an up-to-date problem list. The denominator for this objective is the number of unique patients seen by the EP or admitted to an inpatient facility/department (POS 21) that falls under the eligible hospital's CCN during the EHR reporting period. As this objective relies solely on a capability included as part of certified EHR technology and is not reliant on the electronic exchange of information, we propose to set the percentage required for successful demonstration at 80 percent. The reasoning for this is the same as under CPOE for EPs. Though full compliance (that is, 100 percent) is the ultimate goal, 80 percent seemed an appropriate standard for Stage 1 meaningful use as it creates a high standard, while still allowing room for technical hindrances and other barriers to reaching full compliance.

EP/Eligible Hospital Objective: Maintain active medication allergy list.

EP/Eligible Hospital Measure: At least 80 percent of all unique patients seen by the EP or admitted to the eligible hospital have at least one entry (or an indication of "none" if the patient has no medication allergies) recorded as structured data.

The capability to maintain an active medication allergy list using structured data is included in the certification standards for certified EHR technology (to be defined by ONC in its upcoming interim final rule). Meaningful use seeks to ensure that those capabilities are utilized. Therefore, we believe in order to meet this objective it is not sufficient to demonstrate this capability once, but rather to comply with the objective, an EP or eligible hospital must utilize this capability as part of the daily work process.

As discussed under CPOE, we will use a percentage. To calculate the percentage, CMS and ONC have worked together to define the following for this objective:

- The numerator.
- The denominator.

- The required percentage for demonstrating successful attainment of an objective.

The numerator for this objective is the number of unique patients seen by the EP or admitted to an inpatient facility/department (POS 21) that falls under the eligible hospital's CCN during the EHR reporting period who have at least one entry (or an indication of "none") recorded as structured data in their medication allergy list. A unique patient is discussed under the objective of maintaining an up-to-date problem list. The denominator for this objective is the number of unique patients seen by the EP or admitted to an inpatient facility/department (POS 21) that falls under the eligible hospital's CCN during the EHR reporting period. As this objective relies solely on a capability included as part of certified EHR technology and is not reliant on the electronic exchange of information, we propose to set the percentage required for successful demonstration at 80 percent. The reasoning for this is the same as under CPOE for EPs. Though full compliance (that is, 100 percent) is the ultimate goal, 80 percent seemed an appropriate standard for Stage 1 meaningful use as it creates a high standard, while still allowing room for technical hindrances and other barriers to reaching full compliance.

EP/Eligible Hospital Objective: Record demographics.

EP/Eligible Hospital Measure: At least 80 percent of all unique patients seen by the EP or admitted to the eligible hospital have demographics recorded as structured data.

The capability to record demographics as structured data is included in the certification standards for certified EHR technology (to be defined by ONC in its upcoming interim final rule). Meaningful use seeks to ensure that those capabilities are utilized. Therefore, we believe in order to meet this objective it is not sufficient to demonstrate this capability once, but rather to comply with the objective, an EP or eligible hospital must utilize this capability as part of the daily work process.

As discussed under CPOE, we will use a percentage. To calculate the percentage, CMS and ONC have worked together to define the following for this objective:

- The numerator.
- The denominator.
- The required percentage for demonstrating successful attainment of an objective.

The numerator for this objective is the number of unique patients seen by the EP or admitted to an inpatient facility/

department (POS 21) that falls under the eligible hospital's CCN during the EHR reporting period who have all required demographic elements (preferred language, insurance type, gender, race, and ethnicity, date of birth and, for hospitals, date and cause of death in the case of mortality) recorded as structured data in their electronic record. A unique patient is discussed under the objective of maintaining an up-to-date problem list. The denominator for this objective is the number of unique patients seen by the EP or admitted to an inpatient facility/department (POS 21) that falls under the eligible hospital's CCN during the EHR reporting period. As this objective relies solely on a capability included as part of certified EHR technology and is not, for purposes of Stage 1 criteria, reliant on the electronic exchange of information, we propose to set the percentage required for successful demonstration at 80 percent. The reasoning for this is the same as under CPOE for EPs.

EP/Eligible Hospital Objective: Record and chart changes in vital signs.

EP/Eligible Hospital Measure: For at least 80 percent of all unique patients age 2 and over seen by the EP or admitted to the eligible hospital, record blood pressure and BMI; additionally, plot growth chart for children age 2 to 20.

The capability to record vital signs is included in the certification standards for certified EHR technology (to be defined by ONC in its upcoming interim final rule). Meaningful use seeks to ensure that those capabilities are utilized. Therefore, we believe in order to meet this objective it is not sufficient to demonstrate this capability once, but rather to comply with the objective, an EP or eligible hospital must utilize this capability as part of the daily work process.

As discussed under CPOE, we will use a percentage. To calculate the percentage, CMS and ONC have worked together to define the following for this objective:

- The numerator.
- The denominator.
- The required percentage for demonstrating successful attainment of an objective.

The numerator for this objective is the number of unique patients age 2 and over seen by the EP or admitted to an inpatient facility/department (POS 21) that falls under the eligible hospital's CCN during the EHR reporting period who have a record of their blood pressure, and BMI (growth chart for children 2–20) in their record. A unique patient is discussed under the objective of maintaining an up-to-date problem

list. The denominator for this objective is the number of unique patients age 2 or over seen by the EP or admitted to an inpatient facility/department (POS 21) that falls under the eligible hospital's CCN during the EHR reporting period. As this objective relies solely on a capability included as part of certified EHR technology and is not, for purposes of Stage 1 criteria, reliant on the electronic exchange of information, we propose to set the percentage required for successful demonstration at 80 percent. The reasoning for this is the same as under CPOE for EPs. Though full compliance (that is, 100 percent) is the ultimate goal, 80 percent seemed an appropriate standard for Stage 1 meaningful use as it creates a high standard, while still allowing room for technical hindrances and other barriers to reaching full compliance.

EP/Eligible Hospital Objective: Record smoking status for patients 13 years old or older.

EP/Eligible Hospital Measure: At least 80 percent of all unique patients 13 years old or older seen by the EP or admitted to the eligible hospital have "smoking status" recorded.

The capability to record smoking status is included in the certification standards for certified EHR technology (to be defined by ONC in its upcoming interim final rule). Meaningful use seeks to ensure that those capabilities are utilized. Therefore, we believe in order to meet this objective it is not sufficient to demonstrate this capability once, but rather to comply with the objective, an EP or eligible hospital must utilize this capability as part of the daily work process.

As discussed under CPOE, we will use a percentage. To calculate the percentage, CMS and ONC have worked together to define the following for this objective:

- The numerator.
- The denominator.
- The required percentage for

demonstrating successful attainment of an objective.

The numerator for this objective is the number of unique patients age 13 or older seen by the EP or admitted to an inpatient facility/department (POS 21) that falls under the eligible hospital's CCN during the EHR reporting period who have a record of their smoking status. A unique patient is discussed under the objective of maintaining an up-to-date problem list. The denominator for this objective is the number of unique patients age 13 or older seen by the EP or admitted to an inpatient facility/department (POS 21) that falls under the eligible hospital's CCN during the EHR reporting period.

As this objective relies solely on a capability included as part of certified EHR technology and is not, for purposes of Stage 1 criteria, reliant on the electronic exchange of information, we propose to set the percentage required for successful demonstration at 80 percent. The reasoning for this is the same as under CPOE by the EP. Though full compliance (that is, 100 percent) is the ultimate goal, 80 percent seemed an appropriate standard for Stage 1 meaningful use as it creates a high standard, while still allowing room for technical hindrances and other barriers to reaching full compliance.

EP/Eligible Hospital Objective: Incorporate clinical lab-test results into EHR as structured data.

EP/Eligible Hospital Measure: At least 50 percent of all clinical lab tests results ordered by the EP or by an authorized provider of the eligible hospital during the EHR reporting period whose results are in either in a positive/negative or numerical format are incorporated in certified EHR technology as structured data.

The capability to incorporate lab-test results is included in the certification standards for certified EHR technology (to be defined by ONC in its upcoming interim final rule). Meaningful use seeks to ensure that those capabilities are utilized. Therefore, we believe in order to meet this objective it is not sufficient to demonstrate this capability once, but rather to comply with the objective, an EP or eligible hospital must utilize this capability as part of the daily work process.

As discussed under CPOE, we will use a percentage. To calculate the percentage, CMS and ONC have worked together to define the following for this objective:

- The numerator.
- The denominator.
- The required percentage for

demonstrating successful attainment of an objective.

The numerator for this objective is the number of lab tests ordered during the EHR reporting period by the EP or authorized providers of the eligible hospital for patients admitted to an inpatient facility/department (POS 21) that falls under the eligible hospital's CCN whose results are expressed in a positive or negative affirmation or as a number and are incorporated as structured data into certified EHR technology. The denominator for this objective is the number of lab tests ordered during the EHR reporting period by the EP or authorized providers of the eligible hospital for patients admitted to an inpatient facility/department (POS 21) that falls

under the eligible hospital's CCN whose results are expressed in a positive or negative affirmation or as a number. This objective is reliant on the electronic exchange of information. We are cognizant that in most areas of the country, the infrastructure necessary to support such exchange is still being developed. Therefore, we believe that 80 percent is too high a threshold for the Stage 1 criteria of meaningful use. We propose 50 percent as the threshold based on our discussions with EHR vendors, current EHR users, and laboratories. We invite comment on whether this 50 percent is feasible for the Stage 1 criteria of meaningful use. We anticipate raising the threshold for this objective in future stages of the criteria of meaningful use as the capabilities of HIT infrastructure increases.

EP/Eligible Hospital Objective: Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, research, and outreach.

EP/Eligible Hospital Measure: Generate at least one report listing patients of the EP or eligible hospital with a specific condition.

The capability to generate lists of patients by specific conditions is included in the certification criteria for certified EHR technology (to be defined by ONC in its upcoming interim final rule). Meaningful use seeks to ensure that those capabilities are utilized. Therefore, we believe in order to meet this objective an EP or eligible hospital should utilize this capability at least once during the EHR reporting period so this information would be available to them for their use. An EP or eligible hospital is best positioned to determine which reports are most useful to their care efforts. Therefore, we do not propose to direct certain reports be created, but rather to require EPs and hospitals to attest to the ability of the EP or eligible hospital to do so and to attest that they have actually done so at least once.

EP Objective: Report ambulatory quality measures to CMS or the States.

EP Measure: For 2011, an EP would provide the aggregate numerator and denominator through attestation as discussed in section II.A.3 of this proposed rule. For 2012, an EP would electronically submit the measures are discussed in section II.A.3. of this proposed rule.

Eligible Hospital Objective: Report hospital quality measures to CMS or the States.

Eligible Hospital Measure: For 2011, an eligible hospital would provide the aggregate numerator and denominator

through attestation as discussed in section II.A.3 of this proposed rule. For 2012, an eligible hospital would electronically submit the measures are discussed in section II.A.3. of this proposed rule.

EP Objective: Send reminders to patients per patient preference for preventive/follow-up care.

EP Measure: Reminder sent to at least 50 percent of all unique patients seen by the EP or admitted to the eligible hospital that are 50 and over.

The capability to generate reminders for preventive/follow-up care is included in the certification standards for certified EHR technology (to be defined by ONC in its upcoming interim final rule). Meaningful use seeks to ensure that those capabilities are utilized. Therefore, we believe in order to meet this objective it is not sufficient to demonstrate this capability once, but rather to comply with the objective an EP must utilize this capability as part of the daily work process.

As discussed under CPOE, we will use a percentage. To calculate the percentage, CMS and ONC have worked together to define the following for this objective:

- The numerator.
- The denominator.
- The required percentage for demonstrating successful attainment of an objective.

The numerator for this objective is the number of unique patients age 50 or over seen by the EP during the EHR reporting period who are provided reminders. A unique patient is discussed under the objective of maintaining an up-to-date problem list. We propose to limit the patient population for this measure to patients age 50 or over as they are more likely than the norm to require additional preventive or follow-up care. The denominator for this objective is the number of unique patients seen by the EP during the EHR reporting period. We propose to set the percentage required for successful demonstration at 50 percent. While the objective relies on a capability included as part of certified EHR technology there is still the added component of determining patient preference. Also while we believe we greatly increase the likelihood that additional preventive or follow up care will be required by limiting the patient population to age 50 or over, there may still be instances where there is not an additional preventive or follow up care step needed. For these reasons, we propose the lower threshold of 50 percent. We specifically invite comments on whether limiting the

patient population by age is the best approach.

EP/Eligible Hospital Objective: Implement five clinical decision support rules relevant to specialty or high clinical priority, including for diagnostic test ordering, along with the ability to track compliance with those rules.

EP/Eligible Hospital Measure: Implement five clinical decision support rules relevant to the clinical quality metrics the EP/Eligible Hospital is responsible for as described further in section II.A.3.

The capability to provide clinical decision support is included in the certification standards for certified EHR technology (to be defined by ONC in its upcoming interim final rule). Clinical decision support at the point of care is a critical aspect of improving quality, safety, and efficiency. Research has shown that decision support must be targeted and actionable to be effective, and that "alert fatigue" must be avoided. Establishing decision supports for a small set of high priority conditions, ideally linked to quality measures being reported, is feasible and desirable. Meaningful use seeks to ensure that those capabilities are utilized. Therefore, we believe in order to meet this objective an EP or eligible hospital should implement five clinical decision support rules relevant to the clinical quality metrics described in section II.A.3 before the end of the EHR reporting period and attest to that implementation.

EP/Eligible Hospital Objective: Check insurance eligibility electronically from public and private payers.

EP/Eligible Hospital Measure: Insurance eligibility checked electronically for at least 80 percent of all unique patients seen by the EP or admitted to an eligible hospital.

The capability to check insurance eligibility electronically is included in the certification criteria for certified EHR technology (to be defined by ONC in its upcoming interim final rule). Meaningful use seeks to ensure that those capabilities are utilized. Therefore, we believe in order to meet this objective it is not sufficient to demonstrate this capability once, but rather to comply with the objective an EP or eligible hospital must utilize this capability as part of the daily work process.

As discussed under CPOE, we will use a percentage. To calculate the percentage, CMS and ONC have worked together to define the following for this objective:

- The numerator.
- The denominator.

- The required percentage for demonstrating successful attainment of an objective.

The numerator for this objective is the number of unique patients seen by the EP or admitted to an inpatient facility/department (POS 21) that falls under the eligible hospital's CCN during the EHR reporting period whose insurance eligibility is checked electronically. A unique patient is discussed under the objective of maintaining an up-to-date problem list. The denominator for this objective is the number of unique patients seen by the EP or admitted to an inpatient facility/department (POS 21) that falls under the eligible hospital's CCN during the EHR reporting period whose insurer allows for the electronic verification of eligibility. While this objective does rely on the electronic exchange of information this particular exchange is an established HIPAA standard transaction, therefore we propose to set the percentage required for successful demonstration at 80 percent. The additional reasoning for this is the same as under CPOE for EPs. Though full compliance (that is, 100 percent) is the ultimate goal, 80 percent seemed an appropriate standard for Stage 1 meaningful use as it creates a high standard, while still allowing room for technical hindrances and other barriers to reaching full compliance.

EP/Eligible Hospital Objective: Submit claims electronically to public and private payers.

EP/Eligible Hospital Measure: At least 80 percent of all claims filed electronically by the EP or the eligible hospital.

The capability to submit claims electronically to public and private payers is included in the certification criteria for certified EHR technology (to be defined by ONC in its upcoming interim final rule). Meaningful use seeks to ensure that those capabilities are utilized. Therefore, we believe in order to meet this objective it is not sufficient to demonstrate this capability once, but rather to comply with the objective, an EP or eligible hospital must utilize this capability as part of the daily work process.

As discussed under CPOE, we will use a percentage. To calculate the percentage, CMS and ONC have worked together to define the following for this objective:

- The numerator.
- The denominator.
- The required percentage for demonstrating successful attainment of an objective.

The numerator for this objective is the number of claims submitted

electronically using certified EHR technology for patients seen by the EP or admitted to an inpatient facility/department (POS 21) that falls under the eligible hospital's CCN during the EHR reporting period. The denominator for this objective is the number of claims filed seen by the EP or admitted to an inpatient facility/department (POS 21) that falls under the eligible hospital's CCN during the EHR reporting period. While this objective relies on the electronic exchange of information, nearly all public and private payers accept electronic claims. Given the advance state of this aspect of electronic exchange of information, we propose to set the percentage required for successful demonstration at 80 percent. The additional reasoning for this is the same as under CPOE for EPs. Though full compliance (that is, 100 percent) is the ultimate goal, 80 percent seemed an appropriate standard for Stage 1 meaningful use as it creates a high standard, while still allowing room for technical hindrances and other barriers to reaching full compliance.

EP Objective: Provide patients with an electronic copy of their health information (including diagnostic test results, problem list, medication lists, and allergies) upon request.

Eligible Hospital Objective: Provide patients with an electronic copy of their health information (including diagnostic test results, problem list, medication lists, allergies, discharge summary, and procedures), upon request.

EP/Eligible Hospital Measure: At least 80 percent of all patients who request an electronic copy of their health information are provided it within 48 hours.

The capability to create an electronic copy of a patient's health information is included in the certification criteria for certified EHR technology (to be defined by ONC in its upcoming interim final rule). Meaningful use seeks to ensure that those capabilities are utilized. Therefore, we believe in order to meet this objective it is not sufficient to demonstrate this capability once, but rather to comply with the objective, an EP or eligible hospital must utilize this capability as part of the daily work process. In addition, all patients have a right under ARRA to an electronic copy of their health information. This measure seeks to ensure that this requirement is met in a timely fashion. Providing patients with an electronic copy of their health information demonstrates one of the many benefits health information technology can provide and we believe that it is an important part of becoming a meaningful EHR user. We also believe

that certified EHR technology will provide EPs and eligible hospitals more efficient means of providing copies of health information to patients which is why we have proposed that a request for an electronic copy be provided to the patient within 48 hours.

As discussed under CPOE, we will use a percentage. To calculate the percentage, CMS and ONC have worked together to define the following for this objective:

- The numerator.
- The denominator.
- The required percentage for demonstrating successful attainment of an objective.

The numerator for this objective is the number of patients seen by the EP or admitted to an inpatient facility/department (POS 21) that falls under the eligible hospital's CCN during the EHR reporting period that request an electronic copy of their health information and receive it within 48 hours. The denominator for this objective is the number of patients seen by the EP or admitted to an inpatient facility/department (POS 21) that falls under the eligible hospital's CCN who request an electronic copy of their health information during the EHR reporting period. As this objective relies solely on a capability included as part of certified EHR technology and is not, for purposes of Stage 1 criteria, reliant on the electronic exchange of structured information between health care providers, we propose to set the percentage required for successful demonstration at 80 percent. The reasoning for this is the same as under CPOE for EPs. Though full compliance (that is, 100 percent) is the ultimate goal, 80 percent seemed an appropriate standard for Stage 1 meaningful use as it creates a high standard, while still allowing room for technical hindrances and other barriers to reaching full compliance.

Eligible Hospital Objective: Provide patients with an electronic copy of their discharge instructions and procedures at time of discharge, upon request.

Eligible Hospital Measure: At least 80 percent of all patients who are discharged from an eligible hospital and who request an electronic copy of their discharge instructions and procedures are provided it.

The capability to produce an electronic copy of discharge instructions and procedures is included in the certification criteria for certified EHR technology (to be defined by ONC in its upcoming interim final rule). Meaningful use seeks to ensure that those capabilities are utilized. Therefore, we believe in order to meet

this objective it is not sufficient to demonstrate this capability once, but rather to comply with the objective an eligible hospital must utilize this capability as part of the daily work process.

As discussed under CPOE, we will use a percentage. To calculate the percentage, CMS and ONC have worked together to define the following for this objective:

- The numerator.
- The denominator.
- The required percentage for demonstrating successful attainment of an objective.

The numerator for this objective is the number of patients discharged from an inpatient facility/department (POS 21) that falls under the eligible hospital's CCN during the EHR reporting period that request an electronic copy of their discharge instructions and procedures and receive it. The denominator for this objective is the number of patients discharged from an inpatient facility/department (POS 21) that falls under the eligible hospital's CCN who request an electronic copy of their discharge instructions and procedures during the EHR reporting period. As this objective relies solely on a capability included as part of certified EHR technology and is not, for purposes of Stage 1 criteria, reliant on the electronic exchange of structured information, we propose to set the percentage required for successful demonstration at 80 percent. The reasoning for this is the same as under CPOE for EPs. Though full compliance (that is, 100 percent) is the ultimate goal, 80 percent seemed an appropriate standard for Stage 1 meaningful use as it creates a high standard, while still allowing room for technical hindrances and other barriers to reaching full compliance.

EP Objective: Provide patients with timely electronic access to their health information (including lab results, problem list, medication lists, allergies).

EP Measure: At least 10 percent of all unique patients seen by the EP are provided timely electronic access to their health information

The capability to provide timely electronic access to health information is included in the certification criteria for certified EHR technology (to be defined by ONC in its upcoming interim final rule). Meaningful use seeks to ensure that those capabilities are utilized. Therefore, we believe in order to meet this objective it is not sufficient to demonstrate this capability once, but rather to comply with the objective, an EP must utilize this capability as part of the daily work process.

As discussed under CPOE, we will use a percentage. To calculate the percentage, CMS and ONC have worked together to define the following for this objective:

- The numerator.
- The denominator.
- The required percentage for demonstrating successful attainment of an objective.

The numerator for this objective is the number of unique patients seen during the EHR reporting period who have timely, electronic access to their health information (for example, have established a user account and password on a patient portal). A unique patient is discussed under the objective of maintaining an up-to-date problem list. The denominator for this objective is the number of unique patients seen during the EHR reporting period. We recognize that many patients may not have internet access, may not be able or interested to use a patient portal. Health systems that have actively promoted such technologies have been able to achieve active use by over 30 percent of their patients, but this may not be realistic for many practices in the short term.

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

EP Measure: Clinical summaries provided to patients for at least 80 percent of all office visits.

The capability to provide a clinical summary is included in the certification standards for certified EHR technology (to be defined by ONC in its upcoming interim final rule). Meaningful use seeks to ensure that those capabilities are utilized. Therefore, we believe in order to meet this objective it is not sufficient to demonstrate this capability once, but rather to comply with the objective, an EP must utilize this capability as part of the daily work process.

As discussed under CPOE, we will use a percentage. To calculate the percentage, CMS and ONC have worked together to define the following for this objective:

- The numerator.
- The denominator.
- The required percentage for demonstrating successful attainment of an objective.

The numerator for this objective is the number of unique patients seen in the office during the EHR reporting period who are provided a clinical summary of their visit. A unique patient is discussed under the objective of maintaining an up-to-date problem list. The clinical summary can be provided through a PHR, patient portal on the Web site, secure e-mail, electronic media such as

CD or USB fob, or printed copy. The after-visit clinical summary contains an updated medication list, laboratory and other diagnostic test orders, procedures and other instructions based on clinical discussions that took place during the office visit. The denominator for this objective is the number of unique patients seen in the office during the EHR reporting period. As this objective relies solely on a capability included as part of certified EHR technology and is not, for purposes of Stage 1 criteria, reliant on the electronic exchange of structured information, we propose to set the percentage required for successful demonstration at 80 percent. The reasoning for this is the same as under CPOE for EPs. Though full compliance (that is, 100 percent) is the ultimate goal, 80 percent seemed an appropriate standard for Stage 1 meaningful use as it creates a high standard, while still allowing room for technical hindrances and other barriers to reaching full compliance.

EP Objective: Capability to exchange key clinical information (for example, problem list, medication list, allergies, and diagnostic test results), among providers of care and patient authorized entities electronically.

Eligible Hospital Objective: Capability to exchange key clinical information (for example, discharge summary, procedures, problem list, medication list, allergies, diagnostic test results), among providers of care and patient authorized entities electronically.

EP/Eligible Hospital Measure: Performed at least one test of certified EHR technology's capacity to electronically exchange key clinical information.

The capability to send key clinical information electronically is included in the certification criteria for certified EHR technology (to be defined by ONC in its upcoming interim final rule). Meaningful use seeks to ensure that those capabilities are utilized. However, this objective is reliant on the electronic exchange of information. We are cognizant that in most areas of the country, the infrastructure necessary to support such exchange is still being developed. Therefore, for the Stage 1 criteria of meaningful use we propose that EPs and eligible hospitals test their ability to send such information at least once prior to the end of the EHR reporting period. The testing could occur prior to the beginning of the EHR reporting period. If multiple EPs are using the same certified EHR technology in a shared physical setting, the testing would only have to occur once for a given certified EHR technology, as we do not see any value to running the

same test multiple times just because multiple EPs use the same certified EHR technology. To be considered an "exchange" in this section alone the clinical information must be sent between different clinical entities with distinct certified EHR technology and not between organizations that share a certified EHR.

EP/Eligible Hospital Objective: Perform medication reconciliation at relevant encounters and each transition of care.

EP/Eligible Hospital Measure: Perform medication reconciliation for at least 80 percent of relevant encounters and transitions of care.

The capability to perform medication reconciliation is included in the certification standards for certified EHR technology (to be defined by ONC in its upcoming interim final rule). Meaningful use seeks to ensure that those capabilities are utilized. Therefore, we believe in order to meet this objective it is not sufficient to demonstrate this capability once, but rather to comply with the objective, an EP or eligible hospital must utilize this capability as part of the daily work process.

As discussed under CPOE, we will use a percentage. To calculate the percentage, CMS and ONC have worked together to define the following for this objective:

- The numerator.
- The denominator.
- The required percentage for demonstrating successful attainment of an objective.

The numerator for this objective is the number of relevant encounters and transitions of care for which the EP or an inpatient facility/department (POS 21) that falls under the eligible hospital's CCN was a participant during the EHR reporting period where medication reconciliation was performed. Relevant encounter and transition of care are defined in the previous discussion of this objective in this proposed rule. The denominator for this objective is the number of relevant encounters and transitions of care for which the EP or an inpatient facility/department (POS 21) that falls under the eligible hospital's CCN was a participant during the EHR reporting period. As this objective relies solely on a capability included as part of certified EHR technology and is not, for the purposes of Stage 1 criteria, reliant on the electronic exchange of information, we propose to set the percentage required for successful demonstration at 80 percent. The reasoning for this is the same as under CPOE for EPs. Though full compliance (that is, 100 percent) is

the ultimate goal, 80 percent seemed an appropriate standard for Stage 1 meaningful use as it creates a high standard, while still allowing room for technical hindrances and other barriers to reaching full compliance.

EP/Eligible Hospital Objective:

Provide summary care record for each transition of care and referral.

EP/Eligible Hospital Measure: Provide summary of care record for at least 80 percent of transitions of care and referrals.

The capability to provide a summary of care record is included in the certification standards for certified EHR technology (to be defined by ONC in its upcoming interim final rule). Meaningful use seeks to ensure that those capabilities are utilized. Therefore, we believe in order to meet this objective it is not sufficient to demonstrate this capability once, but rather to comply with the objective an EP or eligible hospital must utilize this capability as part of the daily work process.

As discussed under CPOE, we will use a percentage. To calculate the percentage, CMS and ONC have worked together to define the following for this objective:

- The numerator.
- The denominator.
- The required percentage for demonstrating successful attainment of an objective.

The numerator for this objective is the number of transitions of care and referrals for which the EP or an inpatient facility/department (POS 21) that falls under the eligible hospital's CCN was the transferring or referring provider during the EHR reporting period where a summary of care record was provided. Summary of care record and transitions of care are defined in the discussion of this objective in this proposed rule. The summary of care record can be provided through an electronic exchange, accessed through a secure portal, secure e-mail, electronic media such as CD or USB fob, or printed copy. The denominator for this objective is the number of transitions of care for which the EP or an inpatient facility/department (POS 21) that falls under the eligible hospital's CCN was the transferring or referring provider during the EHR reporting period. As this objective can be completed with or without the use of electronic exchange of information, we propose to set the percentage required for successful demonstration at 80 percent. The reasoning for this is the same as under CPOE for EPs. Though full compliance (that is, 100 percent) is the ultimate goal, 80 percent seemed an appropriate

standard for Stage 1 meaningful use as it creates a high standard, while still allowing room for technical hindrances and other barriers to reaching full compliance.

EP/Eligible Hospital Objective:

Capability to submit electronic data to immunization registries and actual submission where required and accepted.

EP/Eligible Hospital Measure:

Performed at least one test of certified EHR technology's capacity to submit electronic data to immunization registries.

The capability to send electronic data to immunization registries is included in the certification standards for certified EHR technology (to be defined by ONC in its upcoming interim final rule). Meaningful use seeks to ensure that those capabilities are utilized. However, this objective is reliant on the electronic exchange of information. We are cognizant that in many areas of the country, the infrastructure necessary to support such exchange is still being developed. Therefore, for the Stage 1 criteria of meaningful use we propose that EPs and eligible hospitals test their ability to send such information at least once prior to the end of the EHR reporting period. The testing could occur prior to the beginning of the EHR reporting period. EPs in a group setting using identical certified EHR technology would only need to conduct a single test, not one test per EP. More stringent requirements may be established for EPs and hospitals under the Medicaid program in states where this capability exists. This is just one example of a possible State proposed modification to meaningful use in the Medicaid EHR incentive program. States may propose any modification or addition to CMS in accordance with the discussion in II.A.2.c. of this proposed rule.

Eligible Hospital Objective: Capability to provide electronic submission of reportable lab results to public health agencies and actual submission where it can be received.

Eligible Hospital Measure: Performed at least one test of certified EHR technology capacity to provide electronic submission of reportable lab results to public health agencies (unless none of the public health agencies to which eligible hospital submits such information have the capacity to receive the information electronically).

The capability to send reportable lab results is included in the certification standards for certified EHR technology (to be defined by ONC in its upcoming interim final rule). Meaningful use seeks to ensure that those capabilities are utilized. However, this objective is

reliant on the electronic exchange of information. We are cognizant that in most areas of the country, the infrastructure necessary to support such exchange is still being developed. Therefore, for the Stage 1 criteria of meaningful use we propose that eligible hospitals test their ability to send such information at least once prior to the end of the EHR reporting period. The testing could occur prior to the beginning of the EHR reporting period. More stringent requirements may be established for hospitals under the Medicaid program in States where this capability exists. This is just one example of a possible State proposed modification to meaningful use in the Medicaid EHR incentive program. States may propose any modification or addition to CMS in accordance with the discussion in II.A.2.c. of this proposed rule.

EP/Eligible Hospital Objective:

Capability to provide electronic syndromic surveillance data to public health agencies and actual transmission according to applicable law and practice.

EP/Eligible Hospital Measure:

Performed at least one test of certified EHR technology's capacity to provide electronic syndromic surveillance data to public health agencies (unless none of the public health agencies to which an EP or eligible hospital submits such information have the capacity to receive the information electronically).

The capability to send electronic data to immunization registries is included in the certification standards for certified EHR technology (to be defined by ONC in its upcoming interim final rule). Meaningful use seeks to ensure that those capabilities are utilized. However, this objective is reliant on the electronic exchange of information. We are cognizant that in most areas of the country, the infrastructure necessary to support such exchange is still being developed. Therefore, for the Stage 1 criteria of meaningful use we are proposing that EPs and eligible hospitals test their ability to send such information at least once prior to the end of the EHR reporting period. The testing could occur prior to the beginning of the EHR reporting period. EPs in a group setting using identical certified EHR technology would only need to conduct a single test, not one test per EP. More stringent requirements may be established for EPs and hospitals under the Medicaid program in States where this capability exists. This is just one example of a possible State proposed modification to meaningful use in the Medicaid EHR incentive program. States may propose any

modification or addition to CMS in accordance with the discussion in II.A.2.c. of this proposed rule.

EP/Eligible Hospital Objective: Protect electronic health information maintained using certified EHR technology through the implementation of appropriate technical capabilities.

EP/Eligible Hospital Measure: Conduct or review a security risk analysis in accordance with the requirements under 45 CFR 164.308(a)(1) and implement security updates as necessary.

The capability to protect electronic health information maintained using certified EHR technology is included in the certification standards for certified EHR technology (to be defined by ONC in its upcoming interim final rule). Meaningful use seeks to ensure that those capabilities are utilized. While certified EHR technology provides tools for protecting health information, it is not a full protection solution. Processes and possibly tools outside the scope of certified EHR technology are required. Therefore, for the Stage 1 criteria of

meaningful use we propose that EPs and eligible hospitals conduct or review a security risk analysis of certified EHR technology and implement updates as necessary at least once prior to the end of the EHR reporting period and attest to that conduct or review. The testing could occur prior to the beginning of the EHR reporting period. This is to ensure that the certified EHR technology is playing its role in the overall strategy of the EP or eligible hospital in protecting health information.

TABLE 2—STAGE 1 CRITERIA FOR MEANINGFUL USE

Health outcomes policy priority	Care goals	Stage 1 objectives		Stage 1 measures
		Eligible professionals	Hospitals	
Improving quality, safety, efficiency, and reducing health disparities.	Provide access to comprehensive patient health data for patient's health care team.	Use CPOE	Use of CPOE for orders (any type) directly entered by authorizing provider (for example, MD, DO, RN, PA, NP).	For EPs, CPOE is used for at least 80% of all orders. For eligible hospitals, CPOE is used for 10% of all orders.
	Use evidence-based order sets and CPOE.	Implement drug-drug, drug-allergy, drug-formulary checks.	Implement drug-drug, drug-allergy, drug-formulary checks.	The EP/eligible hospital has enabled this functionality.
	Apply clinical decision support at the point of care.	Maintain an up-to-date problem list of current and active diagnoses based on ICD-9-CM or SNOMED CT®.	Maintain an up-to-date problem list of current and active diagnoses based on ICD-9-CM or SNOMED CT®.	At least 80% of all unique patients seen by the EP or admitted to the eligible hospital have at least one entry or an indication of none recorded as structured data.
	Generate lists of patients who need care and use them to reach out to patients.	Generate and transmit permissible prescriptions electronically (eRx).	At least 75% of all permissible prescriptions written by the EP are transmitted electronically using certified EHR technology.
	Report information for quality improvement and public reporting.	Maintain active medication list.	Maintain active medication list.	At least 80% of all unique patients seen by the EP or admitted to the eligible hospital have at least one entry (or an indication of "none" if the patient is not currently prescribed any medication) recorded as structured data.
		Maintain active medication allergy list.	Maintain active medication allergy list.	At least 80% of all unique patients seen, by the EP or admitted to the eligible hospital have at least one entry or (an indication of "none" if the patient has no medication allergies) recorded as structured data.
		Record demographics .. ○ preferred language ○ insurance type ○ gender ○ race ○ ethnicity ○ date of birth	Record demographics .. ○ preferred language ○ insurance type ○ gender ○ race ○ ethnicity ○ date of birth ○ date and cause of death in the event of mortality	At least 80% of all unique patients seen by the EP or admitted to the eligible hospital have demographics recorded as structured data.

TABLE 2—STAGE 1 CRITERIA FOR MEANINGFUL USE—Continued

Health outcomes policy priority	Care goals	Stage 1 objectives		Stage 1 measures
		Eligible professionals	Hospitals	
Engage patients and families in their health care.	Provide patients and families with timely access to data, knowledge, and tools to make informed decisions and to manage their health.	<p>Record and chart changes in vital signs:</p> <ul style="list-style-type: none"> ○ height ○ weight ○ blood pressure ○ Calculate and display: BMI. ○ Plot and display growth charts for children 2–20 years, including BMI. <p>Record smoking status for patients 13 years old or older.</p> <p>Incorporate clinical lab-test results into EHR as structured data.</p> <p>Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, and outreach.</p> <p>Report ambulatory quality measures to CMS or the States.</p> <p>Send reminders to patients per patient preference for preventive/follow up care.</p> <p>Implement 5 clinical decision support rules relevant to specialty or high clinical priority, including diagnostic test ordering, along with the ability to track compliance with those rules.</p> <p>Check insurance eligibility electronically from public and private payers.</p> <p>Submit claims electronically to public and private payers.</p> <p>Provide patients with an electronic copy of their health information (including diagnostic test results, problem list, medication lists, allergies), upon request.</p>	<p>Record and chart changes in vital signs:</p> <ul style="list-style-type: none"> ○ height ○ weight ○ blood pressure ○ Calculate and display: BMI. ○ Plot and display growth charts for children 2–20 years, including BMI. <p>Record smoking status for patients 13 years old or older.</p> <p>Incorporate clinical lab-test results into EHR as structured data.</p> <p>Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, and outreach.</p> <p>Report hospital quality measures to CMS or the States.</p> <p>.....</p> <p>Implement 5 clinical decision support rules related to a high priority hospital condition, including diagnostic test ordering, along with the ability to track compliance with those rules.</p> <p>Check insurance eligibility electronically from public and private payers.</p> <p>Submit claims electronically to public and private payers.</p> <p>Provide patients with an electronic copy of their health information (including diagnostic test results, problem list, medication lists, allergies, discharge summary, procedures), upon request.</p>	<p>For at least 80% of all unique patients age 2 and over seen by the EP or admitted to eligible hospital, record blood pressure and BMI; additionally plot growth chart for children age 2–20.</p> <p>At least 80% of all unique patients 13 years old or older seen by the EP or admitted to the eligible hospital have “smoking status” recorded.</p> <p>At least 50% of all clinical lab tests ordered whose results are in a positive/negative or numerical format are incorporated in certified EHR technology as structured data.</p> <p>Generate at least one report listing patients of the EP or eligible hospital with a specific condition.</p> <p>For 2011, provide aggregate numerator and denominator through attestation as discussed in section II(A)(3) of this proposed rule.</p> <p>For 2012, electronically submit the measures as discussed in section II(A)(3) of this proposed rule.</p> <p>Reminder sent to at least 50% of all unique patients seen by the EP that are age 50 or over.</p> <p>Implement 5 clinical decision support rules relevant to the clinical quality metrics the EP/Eligible Hospital is responsible for as described further in section II(A)(3).</p> <p>Insurance eligibility checked electronically for at least 80% of all unique patients seen by the EP or admitted to the eligible hospital.</p> <p>At least 80% of all claims filed electronically by the EP or the eligible hospital.</p> <p>At least 80% of all patients who request an electronic copy of their health information are provided it within 48 hours.</p>

TABLE 2—STAGE 1 CRITERIA FOR MEANINGFUL USE—Continued

Health outcomes policy priority	Care goals	Stage 1 objectives		Stage 1 measures
		Eligible professionals	Hospitals	
Improve care coordination.	Exchange meaningful clinical information among professional health care team.	Provide patients with timely electronic access to their health information (including lab results, problem list, medication lists, allergies) within 96 hours of the information being available to the EP.	Provide patients with an electronic copy of their discharge instructions and procedures at time of discharge, upon request.	At least 80% of all patients who are discharged from an eligible hospital and who request an electronic copy of their discharge instructions and procedures are provided it.
		Provide clinical summaries for patients for each office visit.	At least 10% of all unique patients seen by the EP are provided timely electronic access to their health information.
Improve population and public health.	Communicate with public health agencies.	Capability to exchange key clinical information (for example, problem list, medication list, allergies, diagnostic test results), among providers of care and patient authorized entities electronically.	Capability to exchange key clinical information (for example, discharge summary, procedures, problem list, medication list, allergies, diagnostic test results), among providers of care and patient authorized entities electronically.	Performed at least one test of certified EHR technology's capacity to electronically exchange key clinical information.
		Perform medication reconciliation at relevant encounters and each transition of care.	Perform medication reconciliation at relevant encounters and each transition of care.	Perform medication reconciliation for at least 80% of relevant encounters and transitions of care.
		Provide summary care record for each transition of care and referral.	Provide summary care record for each transition of care and referral.	Provide summary of care record for at least 80% of transitions of care and referrals.
		Capability to submit electronic data to immunization registries and actual submission where required and accepted.	Capability to submit electronic data to immunization registries and actual submission where required and accepted.	Performed at least one test of certified EHR technology's capacity to submit electronic data to immunization registries.
		Capability to provide electronic syndromic surveillance data to public health agencies and actual transmission according to applicable law and practice.	Capability to provide electronic submission of reportable lab results (as required by state or local law) to public health agencies and actual submission where it can be received.	Performed at least one test of the EHR system's capacity to provide electronic submission of reportable lab results to public health agencies (unless none of the public health agencies to which eligible hospital submits such information have the capacity to receive the information electronically).
			Capability to provide electronic syndromic surveillance data to public health agencies and actual transmission according to applicable law and practice.	Performed at least one test of certified EHR technology's capacity to provide electronic syndromic surveillance data to public health agencies (unless none of the public health agencies to which an EP or eligible hospital submits such information have the capacity to receive the information electronically).

TABLE 2—STAGE 1 CRITERIA FOR MEANINGFUL USE—Continued

Health outcomes policy priority	Care goals	Stage 1 objectives		Stage 1 measures
		Eligible professionals	Hospitals	
Ensure adequate privacy and security protections for personal health information.	Ensure privacy and security protections for confidential information through operating policies, procedures, and technologies and compliance with applicable law. Provide transparency of data sharing to patient.	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 per 45 CFR 164.308(a)(1) and implement security updates as necessary.

e. Request for Public Comment on Potential Health IT Functionality Measures for Eligible Professionals and Eligible Hospitals in 2013 Payment Year and Subsequent Years

As noted previously, we are cognizant that in most areas of the country, the infrastructure necessary to support the electronic exchange of structured information is not yet currently available. For that reason, we excluded the electronic exchange of structured information from many Stage 1 objectives or set relatively low performance thresholds for measures that do rely on the electronic exchange of structured data. For example, we set the threshold at 50 percent for the incorporation of lab data in structured format, and we excluded other types of diagnostic test data (for example, radiology reports, pathology reports, etc.) from that measure. We also excluded the transmission of orders from the definition of “CPOE use” for Stage 1 criteria.

In future rulemaking (for example, for Stage 2 and Stage 3 criteria), however, we anticipate raising the threshold for these objectives as the capabilities of HIT infrastructure increases. We also anticipate redefining our objectives to include not only the capturing of data in electronic format but also the exchange (both transmission and receipt) of that data in increasingly structured formats. The intent and policy goal with raising these thresholds and expectations is to ensure that meaningful use encourages patient-centric, interoperable health information exchange across provider organizations regardless of provider's business affiliation or EHR platform.

We specifically intend to build up the following health IT functionality measures for Stage 2 meaningful use criteria:

- “CPOE use” will include not only the percentage of orders entered directly

by providers through CPOEs but also the electronic transmission of those orders;

- “Incorporate clinical lab-test results into EHR as structured data” will be expanded to include the full array of diagnostic test data used for the treatment and diagnosis of disease, where feasible, including blood tests, microbiology, urinalysis, pathology tests, radiology, cardiac imaging, nuclear medicine tests, and pulmonary function tests;

- Measures that currently allow the provision and exchange of unstructured data (for example, the provision of clinical care summaries on paper) will require the provision and exchange of electronic and structured data, where feasible;

- Measures that currently require the performance of a capability test (for example, capability to provide electronic syndromic surveillance data to public health agencies) will be revised to require the actual submission of that data;

We invite comment on our intent to propose the above measure for Stage 2 in future rulemaking and also invite comment on any other health IT functionality measures not included in this list.

3. Sections 4101(a) and 4102(a)(1) of HITECH Act: Reporting on Clinical Quality Measures Using EHRs by EPs and Eligible Hospitals

a. General

As discussed in the meaningful use background section, there are three elements of meaningful use. In this section, we discuss the third requirement using its certified EHR technology, the EP or eligible hospital submits to the Secretary, in a form and manner specified by the Secretary, information for the EHR reporting period on clinical quality measures and other measures specified by the Secretary. The submission of other

measures is discussed in section II.A.2.d.2 of this proposed rule and the other two requirements are discussed in section II.A.2.d.1 of this proposed rule.

b. Requirements for the Submission of Clinical Quality Measures by EPs and Eligible Hospitals

Sections 1848(o)(2)(B)(ii) and 1886(n)(3)(B)(ii) of the Act provide that the Secretary may not require the electronic reporting of information on clinical quality measures unless the Secretary has the capacity to accept the information electronically, which may be on a pilot basis.

We do not anticipate that HHS will complete the necessary steps for us to have the capacity to electronically accept data on clinical quality measures from EHRs for the 2011 payment year. It is unlikely that by 2011 there will be adequate testing and demonstration of the ability to receive the required transmitted information on a widespread basis. The capacity to accept information on clinical quality measures also depends upon the Secretary promulgating technical specifications for EHR vendors with respect to the transmission of information on clinical quality measures sufficiently in advance of the EHR reporting period for 2011, so that adequate time has been provided either for such specifications to be certified, or for EHR vendors to code such specifications into certified systems. Therefore, for 2011, we propose that EPs and eligible hospitals use an attestation methodology to submit summary information to CMS on clinical quality measures as a condition of demonstrating meaningful use of certified EHR technology.

From the Medicaid perspective, delaying the onset of clinical quality measures reporting until 2012 addresses concerns about States having the ready infrastructure to receive and store

clinical quality measures data before then. More importantly, we recognize that since Medicaid providers are eligible to receive incentive payments for adopting, implementing, or upgrading certified EHR technology, Medicaid EPs may not be focused on demonstrating meaningful use until 2012 or later.

We anticipate that for the 2012 payment year we will have completed the necessary steps to have the capacity to receive electronically information on clinical quality measures from EHRs including the promulgation of technical specifications for EHR vendors to use for obtaining certification of their systems. Therefore, for the Medicare EHR incentive program, we propose that beginning in CY 2012 an EP using a certified EHR technology or beginning in FY 2012 an eligible hospital using a certified EHR technology, as appropriate for clinical quality measures, must submit information on clinical quality measures electronically in addition to submitting other measures described in section II.2.d.2 of this proposed rule in order for the EP or eligible hospital to be a meaningful EHR user, regardless of whether CY 2012 is their first or second payment year. However, if the Secretary does not have the capacity to accept the information on clinical quality measures electronically in 2012, consistent with sections 1848(o)(2)(B)(ii) and 1886(n)(3)(B)(ii) of the Act, we will continue to rely on an attestation methodology for reporting of clinical quality measures as a requirement for demonstrating meaningful use of certified EHR technology for payment year 2012. Should we not have the capacity to accept information on clinical quality measures electronically in 2012, we will inform the public of this fact by publishing a notice in the **Federal Register** and providing instructions on how this information should be submitted to us.

For purposes of the requirements under sections 1848(o)(2)(A)(iii) and 1886(n)(3)(iii) of the Act, we define "clinical quality measures" to consist of measures of processes, experience, and/or outcomes of patient care, observations or treatment that relate to one or more quality aims for health care such as effective, safe, efficient, patient-centered, equitable, and timely care. We note that certain statutory limitations apply only to the reporting of clinical quality measures, such as the requirement discussed in the previous paragraph prohibiting the Secretary from requiring the electronic reporting of information on clinical quality measures unless the Secretary has the capacity to accept the information

electronically, as well as other statutory requirements for clinical quality measures that are discussed below in section II.A.3.c.1 of this proposed rule. These limitations apply solely to the submission of clinical quality measures, and do not apply to other measures of meaningful EHR use. The proposed clinical quality measures on which EPs or eligible hospitals will be required to submit information using certified EHR technology, the statutory requirements and other considerations that were used to select these proposed measures, and the proposed reporting requirements are described below.

With respect to Medicaid EPs and eligible hospitals, we note that section 1903(t)(6) of the Act recognizes that the demonstration of meaningful use may also include the reporting of clinical quality measures to the States. In the interest of simplifying the program and guarding against duplication of meaningful use criteria, we propose that the clinical quality measures adopted for the Medicare EHR incentive program, listed in Tables 3 and 20, will also apply to EPs and eligible hospitals in the Medicaid EHR incentive program. However, we are including alternative Medicaid-specific measures for use by eligible hospitals as shown in Table 21.

Despite the statutory limitation prohibiting the Secretary from requiring the electronic submission of clinical quality measures if HHS does not have the capacity to accept this information electronically, as previously discussed, the Secretary has broad discretion to establish requirements for meaningful use of certified EHR technology and for the demonstration of such use by EPs and eligible hospitals. Although we propose to first require the electronic submission of information on clinical quality measures in 2012, we do not desire this to delay the use of certified EHR technology by EPs and eligible hospitals to measure and improve clinical quality. Specifically, we believe that the use of those functionalities that support measurement of clinical quality is highly important to an overall goal of the HITECH Act, to improve health care quality. We believe that measurement and acting on the results of such measurement is an important aspect to improving quality.

Accordingly, although we are not proposing under sections 1848(o)(2)(A)(iii) and 1886(n)(3)(A)(iii) of the Act to require that for 2011 EPs and eligible hospitals report clinical quality measures to CMS or States electronically, we propose to require as an additional condition of demonstrating meaningful use of certified EHR technology under sections

1848(o)(2)(A)(i) and 1886(n)(3)(A)(ii) of the Act that EPs and eligible hospitals use certified EHR technology to capture the data elements and calculate the results for the applicable clinical quality measures discussed below. We further propose that EPs and eligible hospitals demonstrate that they have satisfied this requirement during the EHR reporting period for 2011 through attestation. We further propose to require that Medicare EPs and eligible hospital attest to the accuracy and completeness of the numerators and denominators for each of the applicable measure. Finally, in accordance with our authority under sections 1848(o)(C)(i)(V) and 1886(n)(3)(C)(i)(V) of the Act, which grants us broad discretion to specify the means through which EPs and eligible hospitals demonstrate compliance with the meaningful use criteria, we propose that EPs and eligible hospitals demonstrate their use of certified EHR technology to capture the data elements and calculate the results for the applicable clinical quality measures by reporting the results to CMS for all applicable patients. For the Medicaid incentive program, States may accept provider attestations in the same manner to demonstrate meaningful use in 2011. However, we expect that Medicaid providers will qualify for the incentive payment by adopting, implementing, or upgrading to certified EHR technology, and therefore; will not need to attest to meaningful use of EHRs in 2011, for their first payment year.

We recognize that considerable work needs to be done by measure owners and developers with respect to the clinical quality measures included in this proposed rule. This includes completing electronic specifications for measures, implementing such specifications into EHR technology to capture and calculate the results, and implementing the systems, themselves. We also recognize that some measures are further developed than others, as discussed in the proposed measures section. Nevertheless, we believe that overall there is sufficient time to complete work on measures and measures specifications to allow vendors, and EPs and eligible hospitals to implement such systems. Should the necessary work on measure specification not be completed for particular measures according to the timetable we discuss below, it is our intent not to finalize those specific measures.

c. Statutory Requirements and Other Considerations for the Proposed Selection of Clinical Quality Measures Proposed for Electronic Submission by EPs or Eligible Hospitals

(1) Statutory Requirements for the Selection of Clinical Quality Measures Proposed for Electronic Submission by EPs and Eligible Hospitals

Sections 1848(o)(2)(B)(i)(II) and 1886(n)(3)(B)(i) of the Act also require that prior to any clinical quality measure being selected, the Secretary will publish in the **Federal Register** such measure and provide for a period of public comment on such measure. The proposed clinical quality measures for EPs and eligible hospitals for 2011 and 2012 payment are listed in Tables 3 through 21.

For purposes of selecting clinical quality measures on which EPs will be required to submit information using certified EHR technology, section 1848(o)(2)(B)(i)(I) of the Act, as added by section 4101 of the HITECH Act, states that the Secretary shall provide preference to clinical quality measures that have been endorsed by the entity with a contract with the Secretary under section 1890(a) of the Act, as added by section 183 of the Medicare Improvement for Patients and Providers Act (MIPPA) of 2008. For submission of clinical quality measures by eligible hospitals, section 1886(n)(3)(B)(i)(I) of the Act, as added by section 4102(a) of the HITECH Act, requires the Secretary to provide preference to those clinical quality measures that have been endorsed by the entity with a contract with the Secretary under subsection 1890(a) of the Act, as added by section 183 of the MIPPA, or 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 Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) program).

On January 14, 2009, the U.S. Department of Health and Human Services awarded the contract required under section 1890(a) of the Act to the National Quality Forum (NQF). Therefore, when selecting the clinical quality measures EPs must report in order to demonstrate meaningful use of certified EHR technology in accordance with section 1848(o)(2)(B)(i)(I) of the Act, we propose to give preference to the clinical quality measures endorsed by the NQF, including NQF endorsed measures that have previously been selected for the Physician Quality Reporting Initiative (PQRI) program. Similarly when selecting the clinical

quality measures eligible hospitals must report in order to demonstrate meaningful use of certified EHR technology in accordance with section 1886(n)(3)(B)(i)(I) of the Act, we propose to give preference to the clinical quality measures selected from those endorsed by the NQF or that have previously been selected for the RHQDAPU program. In some instances we have proposed measures for EPs and eligible hospitals that are not currently NQF endorsed in an effort to include a broader set of clinical quality measures. However, the HITECH Act does not require the use of NQF endorsed measures, nor limit the measures to those included in PQRI or RHQDAPU. If we, professional societies, or other stakeholders identify clinical quality measures which may be appropriate for the EHR incentive programs, we will consider those measures even if they are not endorsed by the NQF or have not been selected for the PQRI or RHQDAPU programs, subject to the requirement to publish in the **Federal Register** such measure(s) for a period of public comment.

We propose the clinical quality measures for EPs and eligible hospitals in Tables 3 through 21 of this proposed rule for use in the 2011 and 2012 payment years for the Medicare EHR incentive program will be effective 60 days after the publication of the final rule in the **Federal Register**. No changes (that is, additions or deletions of clinical quality measures) will be made after publication of the final rule, except through further rulemaking. However, we may make administrative and/or technical modifications or refinements, such as revisions to the clinical quality measures titles and code additions, corrections, or revisions to the detailed specifications for the 2011 and 2012 payment year measures. The 2011 specifications for user submission of clinical quality measures will be available on our Web site when they are sufficiently developed or finalized. Specifications for the EHR incentive programs, even if already published as a part of another incentive payment programs, must be obtained *only* from the specifications documents for the EHR incentive program clinical quality measures. We note also that the final clinical quality measure specifications for eligible hospitals for any given clinical quality measure may be different from specifications for the same clinical quality measure used for the previously described testing of EHR-based data submission. We are targeting finalization and publication of the detailed specifications documents for all 2011 payment year Medicare EHR

incentive program clinical quality measures for eligible hospitals on the CMS Web site on or before April 1, 2010. We intend that a detailed specifications document for all 2012 payment year Medicare EHR incentive program clinical quality measures for EPs be posted on the our Web site on or before April 1, 2011. This would provide final specifications documents at least 9 months in advance of the start of the applicable payment year for clinical quality measure EHR reporting period. We invite comments on our proposed timelines to post specification documents for these clinical quality measures to the CMS Web site.

(2) Other Considerations for the Proposed Selection of Clinical Quality Measures for Electronic Submission by EPs and Eligible Hospitals

In addition to the requirements under sections 1848(o)(2)(B)(i)(I) and 1886(n)(3)(B)(i)(I) of the Act and the other statutory requirements described above, other considerations that we applied to the selection of the proposed clinical quality measures for electronic submission under the Medicare and Medicaid EHR incentive programs include the following:

- Clinical quality measures that are included in, facilitate alignment with, or allow determination of satisfactory reporting in other Medicare (for example, PQRI or the RHQDAPU program), Medicaid, and Children's Health Insurance Program (CHIP) program priorities.
- Clinical quality measures that are widely applicable to EPs and eligible hospitals based on the services provided for the population of patients seen.
- Clinical quality measures that promote CMS and HHS policy priorities related to improved quality and efficiency of care for the Medicare and Medicaid populations that would allow us to track improvement in care over time. These current and long term priority topics include: Prevention; management of chronic conditions; high cost and high volume conditions; elimination of health disparities; healthcare-associated infections and other conditions; improved care coordination; improved efficiency; improved patient and family experience of care; improved end-of-life/palliative care; effective management of acute and chronic episodes of care; reduced unwarranted geographic variation in quality and efficiency; and adoption and use of interoperable HIT.
- Clinical quality measures that address or relate to known gaps in the quality of care and measures that

through the PQRI program, performed at low or highly variable rates.

- Clinical quality measures that have been recommended to CMS for inclusion in the EHR incentive by FACA committees, such as the HIT Policy Committee.

In addition, we note that the statutory requirements under sections 1848(o) and 1886(n) of the Act discussed above do not provide guidance with respect to the development of the clinical quality measures which may then be submitted to the NQF for endorsement. The basic steps for developing clinical quality measures applicable to EPs may be carried out by a variety of different organizations. We do not believe there needs to be any special restrictions on the type or infrastructure of the organizations carrying out this basic development of EP or eligible hospital measures, such as restricting the initial development to EP or eligible hospital organizations. Any such restriction would unduly limit the basic development of clinical quality measures, and the scope and utility of such measures that may be considered for NQF endorsement as voluntary consensus standards.

With respect to the Children's Health Insurance Program Reauthorization Act (CHIPRA) of 2009 (Pub. L. 111-3) Title IV, section 401 requires that the Secretary publish a core set of clinical quality measures for the pediatric population. To the extent possible, we will align the clinical quality measures selected under this Medicaid EHR incentive program with the measures selected under the CHIPRA core measure set. Included in the proposed definition of meaningful use are nine proposed clinical quality measures that pertain to pediatric providers. Four of the nine measures are also on the list of CHIPRA initial core measures that were recommended to the Secretary by the Subcommittee to AHRQ's National Advisory Committee (SNAC). Not all CHIPRA initial measures recommended to the Secretary are applicable to EHR technology or to the Medicaid EHR incentive payment program. For example, some of the measures are population-based, survey-derived, or

not yet NQF-endorsed. New or additional measures for the next iteration of the CHIPRA core set will have EHR-extractability as a priority. The full CHIPRA core measure set will be published for comment in a forthcoming **Federal Register** notice that is expected out before the end of the year.

However, as many providers, including primary care professionals, hospitals, dentists, and specialists provide care to the pediatric population in the Medicaid and CHIP programs. We saw consistency as paramount to avoid redundancy and duplication for these providers and States.

Provider quality measure reporting under CHIPRA for this initial core measure set will initially be voluntary. The intent is to begin standardizing measurement data collection. Due to the concurrent CHIPRA and ARRA HIT implementation activities, we believe there is an exciting opportunity to align the two programs and strive to create efficiencies for States and pediatric providers, where applicable. As both programs move forward, we will continue to prioritize consistency in measure selection for pediatric providers when possible.

We welcome comments on the inclusion or exclusion of any given clinical quality measure or measures proposed herein in the EHR incentive programs clinical quality measure set for EPs or eligible hospitals for the 2011 and 2012 payment years, and to our approach in selecting clinical quality measures. Our goal is for EPs and eligible hospitals to use EHRs to transmit clinical quality measures to the Secretary that would allow determination of their satisfactory reporting under the PQRI and RHQDAPU programs. Even if the clinical quality measures are not the same for PQRI and RHQDAPU satisfactory reporting and EHR meaningful use, our aim is to encourage EPs and eligible hospitals to use EHRs as the mechanism to report PQRI and RHQDAPU measures rather than reporting measures on claims and other reporting mechanisms. We plan to move to this approach as soon as practicable.

To the extent that the same clinical quality measures are used in the PQRI and RHQDAPU programs and for EHR meaningful use, we believe that this approach would be consistent with the statutory requirement to avoid duplicate reporting to the extent practicable. We believe that allowing the measures reporting for the PQRI and RHQDAPU program to be reported via EHRs would provide an added incentive for EPs and eligible hospitals to adopt EHRs.

In addition, 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 through NQF has a designated party (usually, the measure developer/owner) who has accepted responsibility for maintenance of the clinical quality measure. In general, it is the role of the clinical quality measure owner, developer, or maintainer to make basic changes to a clinical quality measure in terms of the numerator, denominator, and exclusions. However, the clinical quality measures selected for the 2011 and 2012 payment year will be supplemented by CMS technical specifications for EHR submission. As discussed earlier, we propose to post the complete clinical quality measures specifications including technical specifications on our Web site and solicit comment on our approach.

d. Proposed Clinical Quality Measures for Electronic Submission Using Certified EHR Technology by EPs

For the 2011 and 2012 EHR reporting periods, based upon the considerations for selecting clinical quality measures discussed above, we propose the set of clinical quality measures identified in Table 3. The Table 3 lists the applicable PQRI and NQF measure number, title, description, the owner/developer, and a link to existing electronic specifications where applicable. Tables 4 through 19 describes further the reporting requirements of the Core and Specialty measure groups.

BILLING CODE 4210-01-P

TABLE 3: Proposed Clinical Quality Measures for Electronic Submission by Medicare or Medicaid Eligible Professionals for the 2011 and 2012 Payment Year

Measure Number	Clinical Quality Measure Title & Description	Clinical Quality Measure Developer & Contact Information	Electronic Measures Specifications Information	Core/Specialty Measure Group
PQRI 1 NQF 0059	Title: Diabetes Mellitus: Hemoglobin A1c Poor Control in Diabetes Mellitus Description: Percentage of patients aged 18 through 75 years with diabetes mellitus who had most recent hemoglobin A1c greater than 9.0%	National Committee for Quality Assurance (NCQA) Contact Information: www.ncqa.org	http://www.cms.hhs.gov/PQRI/20_AlternativeReportingMechanisms.asp#TopOfPage	Endocrinology, Primary Care
PQRI 2 NQF 0064	Title: Diabetes Mellitus: Low Density Lipoprotein (LDL-C) Control in Diabetes Mellitus Description: Percentage of patients aged 18 through 75 years with diabetes mellitus who had most recent LDL-C level in control (less than 100 mg/dl)	NCQA Contact Information: www.ncqa.org	http://www.cms.hhs.gov/PQRI/20_AlternativeReportingMechanisms.asp#TopOfPage	Endocrinology
PQRI 3 NQF 0061	Title: Diabetes Mellitus: High Blood Pressure Control in Diabetes Mellitus Description: Percentage of patients aged 18 through 75 years with diabetes mellitus who had most recent blood pressure in control (less than 140/80 mmHg)	NCQA Contact Information: www.ncqa.org	http://www.cms.hhs.gov/PQRI/20_AlternativeReportingMechanisms.asp#TopOfPage	Endocrinology
PQRI 5 NQF 0081	Title: Heart Failure: 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 and LVSD who were prescribed ACE inhibitor or ARB therapy	American Medical Association-sponsored Physician Consortium for Performance Improvement (AMA-PCPI) Contact Information: cpe@ama-assn.org	http://www.cms.hhs.gov/PQRI/20_AlternativeReportingMechanisms.asp#TopOfPage	Cardiology
PQRI 7 NQF 0070	Title: Coronary Artery Disease (CAD): Beta-Blocker Therapy for CAD Patients with Prior Myocardial Infarction (MI) Description: Percentage of patients aged 18 years and older with a diagnosis of CAD and prior MI who were prescribed beta-blocker therapy	AMA-PCPI Contact Information: cpe@ama-assn.org	http://www.cms.hhs.gov/PQRI/20_AlternativeReportingMechanisms.asp#TopOfPage	Cardiology
PQRI 110 NQF 0041	Title: Preventive Care and Screening: Influenza Immunization for Patients ≥ 50 Years Old Description: Percentage of patients aged 50 years and older who received an influenza immunization during the flu season (September through February)	AMA-PCPI Contact Information: cpe@ama-assn.org	http://www.cms.hhs.gov/PQRI/20_AlternativeReportingMechanisms.asp#TopOfPage	Primary Care

Measure Number	Clinical Quality Measure Title & Description	Clinical Quality Measure Developer & Contact Information	Electronic Measure Specifications Information	Core/Specialty Measure Group
PQRI 111 NQF 0043	Title: Preventive Care and Screening: Pneumonia Vaccination for Patients 65 Years and Older Description: Percentage of patients aged 65 years and older who have ever received a pneumococcal vaccine	NCQA Contact Information: www.ncqa.org	http://www.cms.hhs.gov/PQRI/20_AlternativeReportingMechanisms.asp#TOPPage	Pulmonology
PQRI 112 NQF 0031	Title: Preventive Care and Screening: Screening Mammography Description: Percentage of women aged 40 through 69 years who had a mammogram to screen for breast cancer within 24 months	NCQA Contact Information: www.ncqa.org	http://www.cms.hhs.gov/PQRI/20_AlternativeReportingMechanisms.asp#TOPPage	Oncology, Primary Care, Obstetrics and Gynecology
PQRI 113 NQF 0034	Title: Preventive Care and Screening: Colorectal Cancer Screening Description: Percentage of patients aged 50 through 80 years who received the appropriate colorectal cancer screening	NCQA Contact Information: www.ncqa.org	http://www.cms.hhs.gov/PQRI/20_AlternativeReportingMechanisms.asp#TOPPage	Oncology, Primary Care, Gastroenterology
PQRI 6 NQF 0067	Title: Coronary Artery Disease (CAD): Oral Antiplatelet Therapy Prescribed for Patients with CAD Description: Percentage of patients aged 18 years and older with a diagnosis of CAD who were prescribed oral antiplatelet therapy	AMA-PCPI Contact Information: cpe@ama-assn.org		Cardiology
PQRI 8 NQF 0083	Title: Heart Failure: Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD) Description: Percentage of patients aged 18 years and older with a diagnosis of heart failure who also have LVSD and who were prescribed beta-blocker therapy	AMA-PCPI Contact Information: cpe@ama-assn.org		Cardiology
PQRI 9 NQF 0105	Title: Major Depressive Disorder (MDD): Antidepressant Medication During Acute Phase for Patients with MDD Description: Percentage of patients aged 18 years and older diagnosed with new episode of MDD and documented as treated with antidepressant medication during the entire 84-day (12-week) acute treatment phase	NCQA Contact Information: www.ncqa.org		Psychiatry

Measure Number	Clinical Quality Measure Title & Description	Clinical Quality Measure Developer & Contact Information	Electronic Measure Specifications Information	Core/Specialty Measure Group
PQRI 10 NQF 0246	<p>Title: Stroke and Stroke Rehabilitation: Computed Tomography (CT) or Magnetic Resonance Imaging (MRI) Reports</p> <p>Description: Percentage of final reports for CT or MRI studies of the brain performed within 24 hours of arrival to the hospital for patients aged 18 years and older with either a diagnosis of ischemic stroke or transient ischemic attack (TIA) or intracranial hemorrhage or at least one documented symptom consistent with ischemic stroke or TIA or intracranial hemorrhage that includes documentation of the presence or absence or each of the following: hemorrhage and mass lesion and acute infarction.</p>	<p>AMA-PCPI/NCQA</p> <p>Contact Information: cpe@ama-assn.org www.ncqa.org</p>		Radiology
PQRI 12 NQF 0086	<p>Title: Primary Open Angle Glaucoma (POAG): Optic Nerve Evaluation</p> <p>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</p>	<p>AMA-PCPI/NCQA</p> <p>Contact Information: cpe@ama-assn.org www.ncqa.org</p>		Ophthalmology
PQRI 18 NQF 0088	<p>Title: Diabetic Retinopathy: Documentation of Presence or Absence of Macular Edema and Level of Severity of Retinopathy</p> <p>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</p>	<p>AMA-PCPI/NCQA</p> <p>Contact Information: cpe@ama-assn.org www.ncqa.org</p>		Ophthalmology
PQRI 19 NQF 0089	<p>Title: Diabetic Retinopathy: Communication with the Physician Managing On-going Diabetes Care</p> <p>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 on-going care of the patient with diabetes mellitus regarding the findings of the macular or fundus exam at least once within 12 months</p>	<p>AMA-PCPI/NCQA</p> <p>Contact Information: cpe@ama-assn.org www.ncqa.org</p>		Ophthalmology

Measure Number	Clinical Quality Measure Title & Description	Clinical Quality Measure Developer & Contact Information	Electronic Measure Specifications Information	Core/Specialty Measure Group
PQRI 20 NQF 0270	Title: Perioperative Care: Timing of Antibiotic Prophylaxis – Ordering Physician Description: Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for prophylactic parenteral antibiotics, who have an order for prophylactic antibiotic to be given within one hour (if fluoroquinolone or vancomycin, two hours), prior to the surgical incision (or start of procedure when no incision is required)	AMA-PCPI/NCQA Contact Information: cpe@ama-assn.org www.ncqa.org		Proceduralists/Surgery
PQRI 21 NQF 0268	Title: Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second Generation Cephalosporin Description: Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second generation cephalosporin prophylactic antibiotic, who had an order for cefazolin OR cefuroxime for antimicrobial prophylaxis	AMA-PCPI/NCQA Contact Information: cpe@ama-assn.org www.ncqa.org		Proceduralists/Surgery
PQRI 22 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 antibiotics AND who received a prophylactic antibiotic, who have an order for discontinuation of prophylactic antibiotics within 24 hours of surgical end time	AMA-PCPI/NCQA Contact Information: cpe@ama-assn.org www.ncqa.org		Proceduralists/Surgery
PQRI 23 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/NCQA Contact Information: cpe@ama-assn.org www.ncqa.org		Proceduralists/Surgery
PQRI 33 NQF 0241	Title: Stroke and Stroke Rehabilitation: Anticoagulant Therapy Prescribed for Atrial Fibrillation at Discharge Description: Percentage of patients aged 18 years and older with a diagnosis of ischemic stroke or transient ischemic attack (TIA) with documented permanent, persistent, or paroxysmal atrial fibrillation who were prescribed an anticoagulant at discharge	AMA-PCPI/NCQA Contact Information: cpe@ama-assn.org www.ncqa.org		Neurology

Measure Number	Clinical Quality Measure Title & Description	Clinical Quality Measure Developer & Contact Information	Electronic Measure Specifications Information	Core/Specialty Measure Group
PQRI 52 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 an FEV1/FVC less than 70% and have symptoms who were prescribed an inhaled bronchodilator	AMA-PCPI Contact Information: cpe@ama-assn.org		Pulmonology
PQRI 53 NQF 0047	Title: Asthma: Pharmacologic Therapy Description: Percentage of patients aged 5 through 40 years with a diagnosis of mild, moderate, or severe persistent asthma who were prescribed either the preferred long-term control medication (inhaled corticosteroid) or an acceptable alternative treatment	AMA-PCPI Contact Information: cpe@ama-assn.org		Pulmonology
PQRI 65 NQF 0069	Title: Treatment for Children with Upper Respiratory Infection (URI): Avoidance of Inappropriate Use Description: Percentage of children aged 3 months through 18 years with a diagnosis of URI who were not prescribed or dispensed an antibiotic prescription on or within 3 days of the initial date of service	NCQA Contact Information: www.ncqa.org		Primary Care
PQRI 66 NQF 0002	Title: Appropriate Testing for Children with Pharyngitis Description: Percentage of children aged 2 through 18 years with a diagnosis of pharyngitis, who were prescribed an antibiotic and who received a group A streptococcus (strep) test for the episode	NCQA Contact Information: www.ncqa.org		Pediatrics, Primary Care
PQRI 71 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/American Society of Clinical Oncology (ASCO)-National Comprehensive Cancer Network (NCCN): Contact Information: cpe@ama-assn.org http://www.asco.org/		Oncology
PQRI 72 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, prescribed adjuvant chemotherapy, or have previously received adjuvant chemotherapy within the 12-month reporting period	AMA-PCPI/ASCO-NCCN Contact Information: cpe@ama-assn.org http://www.asco.org/		Oncology

Measure Number	Clinical Quality Measure Title & Description	Clinical Quality Measure Developer & Contact Information	Electronic Measure Specifications Information	Core/Specialty Measure Group
PQRI 81 NQF 0323	Title: End Stage Renal Disease (ESRD): Plan of Care for Inadequate Hemodialysis in ESRD Patients Description: Percentage of calendar months during the 12-month reporting period in which patients aged 18 years and older with a diagnosis of ESRD receiving hemodialysis have a Kt/V \geq 1.2 OR patients who have a Kt/V < 1.2 with a documented plan of care for inadequate hemodialysis	AMA-PCPI Contact Information: cpe@ama-assn.org		Nephrology
PQRI 82 NQF 0321	Title: End Stage Renal Disease (ESRD): Plan of Care for Inadequate Peritoneal Dialysis Description: Percentage of patients aged 18 years and older with a diagnosis of ESRD receiving peritoneal dialysis who have a Kt/V \geq 1.7 OR patients who have a Kt/V < 1.7 with a documented plan of care for inadequate peritoneal dialysis at least three times (every 4 months) during the 12-month reporting period	AMA-PCPI Contact Information: cpe@ama-assn.org		Nephrology
PQRI 86 NQF 0397	Title: Hepatitis C: Antiviral Treatment Prescribed Description: Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C who were prescribed peginterferon and ribavirin therapy within the 12-month reporting period	AMA-PCPI Contact Information: cpe@ama-assn.org		Gastroenterology
PQRI 89 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 the 12-month reporting period	AMA-PCPI Contact Information: cpe@ama-assn.org		Gastroenterology
PQRI 102 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		Oncology

Measure Number	Clinical Quality Measure Title & Description	Clinical Quality Measure Developer & Contact Information	Electronic Measure Specifications Information	Core/Specialty Measure Group
PQRI 106 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		Psychiatry
PQRI 107 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		Psychiatry
PQRI 114 NQF 0028	Title: Preventive Care and Screening: Inquiry Regarding Tobacco Use Description: Percentage of patients aged 18 years or older who were queried about tobacco use one or more times within 24 months	AMA-PCPI Contact Information: cpe@ama-assn.org		Core, Pulmonology, Primary Care
PQRI 115 NQF 0027	Title: Preventive Care and Screening: Advising Smokers to Quit Description: Percentage of patients aged 18 years and older and are smokers who received advice to quit smoking	NCQA Contact Information: www.ncqa.org		Pulmonology, Primary Care
PQRI 117 NQF 0055	Title: Diabetes Mellitus: Dilated Eye Exam in Diabetic Patient Description: Percentage of patients aged 18 through 75 years with a diagnosis of diabetes mellitus who had a dilated eye exam	AMA-PCPI Contact Information: cpe@ama-assn.org		Endocrinology
PQRI 118 NQF 0066	Title: Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Patients with CAD and Diabetes and/or Left Ventricular Systolic Dysfunction (LVSD) Description: Percentage of patients aged 18 years and older with a diagnosis of CAD who also have diabetes mellitus and/or LVSD (LVEF < 40%) who were prescribed ACE inhibitor or ARB therapy	AMA-PCPI Contact Information: cpe@ama-assn.org		Cardiology

Measure Number	Clinical Quality Measure Title & Description	Clinical Quality Measure Developer & Contact Information	Electronic Measure Specifications Information	Core/Specialty Measure Group
PQRI 119 NQF 0062	Title: Diabetes Mellitus: Urine Screening for Microalbumin or Medical Attention for Nephropathy in Diabetic Patients Description: Percentage of patients aged 18 through 75 years with diabetes mellitus who received urine protein screening or medical attention for nephropathy during at least one office visit within 12 months	NCQA Contact Information: www.ncqa.org		Endocrinology
PQRI 121 Ambulatory Quality Alliance (AQA) adopted	Title: Chronic Kidney Disease (CKD): Laboratory Testing (Calcium, Phosphorus, Intact Parathyroid Hormone (iPTH) and Lipid Profile) Description: Percentage of patients aged 18 years and older with a diagnosis of advanced CKD (stage 4 or 5, not receiving Renal Replacement Therapy [RRT]), who had the following laboratory testing ordered within 12 months: serum levels of calcium, phosphorus and intact PTH, and lipid profile	AMA-PCPI Contact Information: cpe@ama-assn.org		Nephrology
PQRI 122 AQA adopted	Title: Chronic Kidney Disease (CKD): Blood Pressure Management Description: Percentage of patient visits for patients aged 18 years and older with a diagnosis of advanced CKD (stage 4 or 5, not receiving Renal Replacement Therapy [RRT]), with a blood pressure < 130/80 mmHg OR blood pressure \geq 130/80 mmHg with a documented plan of care	AMA-PCPI Contact Information: cpe@ama-assn.org		Nephrology
PQRI 123 AQA adopted	Title: Chronic Kidney Disease (CKD): Plan of Care – Elevated Hemoglobin for Patients Receiving Erythropoiesis-Stimulating Agents (ESA) Description: Percentage of calendar months during the 12-month reporting period in which patients aged 18 years and older with a diagnosis of advanced CKD (stage 4 or 5, not receiving Renal Replacement Therapy [RRT]), receiving ESA therapy, have a hemoglobin < 13 g/dL OR patients whose hemoglobin is \geq 13 g/dL and have a documented plan of care	AMA-PCPI Contact Information: cpe@ama-assn.org		Nephrology
PQRI 127 NQF 0416	Title: Diabetes Mellitus: Diabetic Foot and Ankle Care, Ulcer Prevention – Evaluation of Footwear Description: Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who were evaluated for proper footwear and sizing	American Podiatric Medical Association (APMA) Contact Information: http://www.apma.org/		Podiatry

Measure Number	Clinical Quality Measure Title & Description	Clinical Quality Measure Developer & Contact Information	Electronic Measure Specifications Information	Core/Specialty Measure Group
PQRI 128 NQF 0421	Title: Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Description: Percentage of patients aged 18 years and older with a calculated BMI in the past six months or during the current visit documented in the medical record AND if the most recent BMI is outside parameters, a follow-up plan is documented Parameters: Age 65 and older BMI ≥ 30 or < 22 Age 18 – 64 BMI ≥ 25 or < 18.5	CMS/Quality Insights of Pennsylvania (QIP) Contact Information: PQRI_inquiry@cms.hhs.gov		Cardiology, Endocrinology, Primary Care, Obstetrics and Gynecology
PQRI 145 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/NCQA Contact Information: cpe@ama-assn.org www.ncqa.org		Radiology
PQRI 146 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/NCQA Contact Information: cpe@ama-assn.org www.ncqa.org		Radiology
PQRI 147 NQF 0511	Title: Nuclear Medicine: Correlation with Existing Imaging Studies for All Patients Undergoing Bone Scintigraphy Description: Percentage of final reports for all patients, regardless of age, undergoing bone scintigraphy that include physician documentation of correlation with existing relevant imaging studies (e.g., x-ray, MRI, CT, etc.) that were performed	AMA-PCPI Contact Information: cpe@ama-assn.org		Radiology
PQRI 153 AQA adopted	Title: Chronic Kidney Disease (CKD): Referral for Arteriovenous (AV) Fistula Description: Percentage of patients aged 18 years and older with the diagnosis of advanced CKD (stage 4 or 5, not receiving Renal Replacement Therapy [RRT]), who were referred for AV fistula at least once during the 12-month reporting period	AMA-PCPI Contact Information: cpe@ama-assn.org		Nephrology
PQRI 163 NQF 0056	Title: Diabetes Mellitus: Foot Exam Description: The percentage of patients aged 18 through 75 years with diabetes who had a foot examination	NCQA Contact Information: www.ncqa.org		Podiatry

Measure Number	Clinical Quality Measure Title & Description	Clinical Quality Measure Developer & Contact Information	Electronic Measure Specifications Information	Core/Specialty Measure Group
PQRI 183 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 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		Gastroenterology
PQRI 184 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 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		Gastroenterology
PQRI 185 AQA adopted	Title: Endoscopy & Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use Description: Percentage of patients aged 18 years and older receiving a surveillance colonoscopy and a history of colonic polyp(s) in a previous colonoscopy, who had a follow-up interval of 3 or more years since their last colonoscopy documented in the colonoscopy report	AMA-PCPI/NCQA Contact Information: cpe@ama-assn.org www.ncqa.org		Gastroenterology
PQRI 195 NQF 0507	Title: Stenosis Measurement in Carotid Imaging Reports Description: Percentage of final reports for carotid imaging studies (neck MR angiography [MRA], neck CT angiography [CTA], neck duplex ultrasound, carotid angiogram) performed for patients aged 18 years and older with the diagnosis of ischemic stroke or transient ischemic attack (TIA) that include direct or indirect reference to measurements of distal internal carotid diameter as the denominator for stenosis measurement	AMA-PCPI/NCQA Contact Information: cpe@ama-assn.org www.ncqa.org		Radiology
PQRI 197 NQF 0074	Title: Coronary Artery Disease (CAD): Drug Therapy for Lowering LDL-Cholesterol Description: Percentage of patients aged 18 years and older with a diagnosis of CAD who were prescribed a lipid-lowering therapy (based on current ACC/AHA guidelines)	AMA-PCPI Contact Information: cpe@ama-assn.org		Cardiology, Primary Care
PQRI 200 NQF 0084	Title: Heart Failure: Warfarin Therapy for Patients with Atrial Fibrillation Description: Percentage of all patients aged 18 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		Cardiology

Measure Number	Clinical Quality Measure Title & Description	Clinical Quality Measure Developer & Contact Information	Electronic Measure Specifications Information	Core/Specialty Measure Group
PQRI 201 NQF 0073	Title: Ischemic Vascular Disease (IVD): Blood Pressure Management Control Description: Percentage of patients aged 18 years and older with Ischemic Vascular Disease (IVD) who had most recent blood pressure in control (less than 140/90 mmHg)	NCQA Contact Information: www.ncqa.org		Neurology
PQRI 202 NQF 0075	Title: Ischemic Vascular Disease (IVD): Complete Lipid Profile Description: Percentage of patients aged 18 years and older with Ischemic Vascular Disease (IVD) who received at least one lipid profile within 12 months	NCQA Contact Information: www.ncqa.org		Primary Care, Neurology
PQRI 203 NQF 0075	Title: Ischemic Vascular Disease (IVD): Low Density Lipoprotein (LDL-C) Control Description: Percentage of patients aged 18 years and older with Ischemic Vascular Disease (IVD) who had most recent LDL-C level in control (less than 100 mg/dl)	NCQA Contact Information: www.ncqa.org		Primary Care, Neurology
PQRI 204 NQF 0068	Title: Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic Description: Percentage of patients aged 18 years and older with Ischemic Vascular Disease (IVD) with documented use of aspirin or other antithrombotic	NCQA Contact Information: www.ncqa.org		Cardiology, Endocrinology, Primary Care, Neurology
NQF 0001	Title: Asthma assessment Description: Percentage of patients who were evaluated during at least one office visit for the frequency (numeric) of daytime and nocturnal asthma symptoms	AMA-PCPI Contact Information: www.ama-assn.org		Pulmonology, Primary Care
NQF 0004	Title: Initiation and Engagement of Alcohol and Other Drug Dependence Treatment: (a) Initiation, (b) Engagement Description: Percentage of adults aged 18 and over diagnosed with AOD abuse or dependence and receiving a related service who initiate treatment Assessment of the degree to which members engage in treatment with two additional AOD treatments within 30 days after initiating treatment.	NCQA Contact Information: www.ncqa.org		Primary Care, Psychiatry
NQF 0012	Title: Prenatal Screening for Human Immunodeficiency Virus (HIV) Description: Percentage of patients 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: www.ama-assn.org		Obstetrics and Gynecology

Measure Number	Clinical Quality Measure Title & Description	Clinical Quality Measure Developer & Contact Information	Electronic Measure Specifications Information	Core/Specialty Measure Group
NQF 0013	Title: Blood pressure measurement Description: Percentage of patient visits with blood pressure measurement recorded among all patient visits for patients aged > 18 years with diagnosed hypertension.	AMA-PCPI Contact Information: www.ama-assn.org		Core
NQF 0014	Title: Prenatal Anti-D Immune Globulin Description: Percentage of D-negative, unsensitized patients who gave birth during a 12-month period who received anti-D immune globulin at 26-30 weeks gestation	AMA-PCPI Contact Information: www.ama-assn.org		Obstetrics and Gynecology
NQF 0018	Title: Controlling High Blood Pressure Description: Percentage of patients with last BP < 140/80 mm Hg.	NCQA Contact Information: www.ncqa.org		Primary Care
NQF 0022	Title: Drugs to be avoided in the elderly: a. Patients who receive at least one drug to be avoided, b. Patients who receive at least two different drugs to be avoided. Description: Percentage of patients ages 65 years and older who received at least one drug to be avoided in the elderly in the measurement year. Percentage of patients 65 years of age and older who received at least two different drugs to be avoided in the elderly in the measurement year.	NCQA Contact Information: www.ncqa.org		Core
NQF 0024	Title: Body Mass Index (BMI) 2 through 18 years of age Description: Percentage children, 2 through 18 years of age, whose weight is classified based on BMI percentile for age and gender	National Initiative for Children's Healthcare Quality Contact Information: http://www.nichq.org/		Pediatrics, Primary Care
NQF 0026	Title: Measure pair - a. Tobacco use prevention for infants, children and adolescents, b. Tobacco use cessation for infants, children and adolescents Description: Percentage of patients' charts showing either that there is no tobacco use/exposure or (if a user) that the current use was documented at the most recent clinic visit. Percentage of patients with documented tobacco use or exposure at the latest visit who also have documentation that their cessation interest was assessed or that they received advice to quit.	Institute for Clinical Systems Improvement (ICSI) Contact Information: http://www.icsi.org/		Pediatrics

Measure Number	Clinical Quality Measure Title & Description	Clinical Quality Measure Developer & Contact Information	Electronic Measure Specifications Information	Core/Specialty Measure Group
NQF 0032	Title: Cervical Cancer Screening Description: Percentage of women 18-64 years of age, who received one or more Pap tests during the measurement year or the 2 years prior to the measurement year.	NCQA <u>Contact Information:</u> www.ncqa.org		Oncology, Primary Care, Obstetrics and Gynecology
NQF 0033	Title: Chlamydia screening in women Description: Percentage of eligible women who were identified as sexually active who had at least one test for chlamydia during the measurement year.	NCQA <u>Contact Information:</u> www.ncqa.org		Obstetrics and Gynecology
NQF 0036	Title: Use of appropriate medications for people with asthma Description: Percentage of patients who were identified as having persistent asthma during the measurement year and the year prior to the measurement year and who were dispensed a prescription for either an inhaled corticosteroid or acceptable alternative medication during the measurement year.	NCQA <u>Contact Information:</u> www.ncqa.org		Pulmonology, Primary Care
NQF 0038	Title: Childhood Immunization Status Description: Percentage of children 2 years of age who had four DtaP/DT, three IPV, one MMR, three H influenza type B, three hepatitis B, one chicken pox vaccine (VZV) and four pneumococcal conjugate vaccines by their second birthday. The measure calculates a rate for each vaccine and two separate combination rates.	NCQA <u>Contact Information:</u> www.ncqa.org		Primary Care, Pediatrics
NQF 0052	Title: Low back pain: use of imaging studies Description: Percentage of patients with new low back pain who received an imaging study (plain x-ray, MRI, CT scan) conducted on the episode start date or in the 28 days following the episode start date.	NCQA <u>Contact Information:</u> www.ncqa.org		Primary Care, Radiology
NQF 0060	Title: Hemoglobin A1c test for pediatric patients Description: Percentage of pediatric patients with diabetes with a HBA1c test in a 12-month measurement period.	NCQA <u>Contact Information:</u> www.ncqa.org		Endocrinology, Pediatrics, Primary Care

Measure Number	Clinical Quality Measure Title & Description	Clinical Quality Measure Developer & Contact Information	Electronic Measure Specifications Information	Core/Specialty Measure Group
NQF 0105	<p>Title: New Episode of Depression: (a) Optimal Practitioner Contacts for Medication Management, (b) Effective Acute Phase Treatment, (c) Effective Continuation Phase Treatment</p> <p>Description: Percentage of patients who were diagnosed with a new episode of depression and treated with antidepressant medication, and who had at least three follow-up contacts with a practitioner during the 84-day (12-week) Acute Treatment</p> <p>Phase b. Percentage of patients who were diagnosed with a new episode of depression, were treated with antidepressant medication and remained on an antidepressant drug during the entire 84-day Acute Treatment</p> <p>Phase c. Percentage of patients who were diagnosed with a new episode of depression and treated with antidepressant medication and who remained on an antidepressant drug for at least 180 days.</p>	<p>NCQA</p> <p>Contact Information: www.ncqa.org</p>		Psychiatry, Primary Care
NQF 0106	<p>Title: Diagnosis of attention deficit hyperactivity disorder (ADHD) in primary care for school age children and adolescents</p> <p>Description: Percentage of patients newly diagnosed with attention deficit hyperactivity disorder (ADHD) whose medical record contains documentation of Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) or Diagnostic and Statistical Manual for Primary Care (DSM-PC) criteria being addressed.</p>	<p>ICSI</p> <p>Contact Information: http://www.icsi.org/</p>		Pediatrics, Primary Care
NQF 0107	<p>Title: Management of attention deficit hyperactivity disorder (ADHD) in primary care for school age children and adolescents</p> <p>Description: Percentage of patients diagnosed with attention deficit hyperactivity disorder (ADHD) and on first-line medication whose medical record contains documentation of a follow-up visit twice a year.</p>	<p>ICSI</p> <p>Contact Information: http://www.icsi.org/</p>		Pediatrics, Primary Care

Measure Number	Clinical Quality Measure Title & Description	Clinical Quality Measure Developer & Contact Information	Electronic Measure Specifications Information	Core/Specialty Measure Group
NQF 0108	<p>Clinical Quality Measure Title & Description</p> <p>Title: ADHD: Follow-Up Care for Children Prescribed Attention-Deficit/Hyperactivity Disorder (ADHD) Medication.</p> <p>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 and ADHD medication and who had one follow-up visit with a practitioner with prescribing authority during the 30-Day Initiation</p> <p>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 ends.</p>	<p>NCQA</p> <p>Contact Information: www.ncqa.org</p>		Pediatrics, Primary Care
NQF 0110	<p>Title: Bipolar Disorder and Major Depression: Appraisal for alcohol or chemical substance use</p> <p>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</p>	<p>Center for Quality Assessment and Improvement in Mental Health</p> <p>Contact Information: http://www.cqaimh.org/</p>		Psychiatry, Primary Care
NQF 0299	<p>Title: Surgical Site Infection Rate</p> <p>Description: Percentage of surgical site infections occurring within thirty days after the operative procedure if no implant is left in place or with one year if an implant is in place in patients who had an NHSN operative procedure performed during a specified time period and the infection appears to be related to the operative procedure.</p>	<p>Centers for Disease Control and Prevention (CDC)</p> <p>Contact Information: http://www.cdc.gov/</p>		Proceduralists/Surgery

Measure Number	Clinical Quality Measure Title & Description	Clinical Quality Measure Developer & Contact Information	Electronic Measure Specifications Information	Core/Specialty Measure Group
NQF 0471	<p>Title: Cesarean Rate for low-risk first birth women (aka NTSV CS rate)</p> <p>Description: Percentage of low-risk first birth women (aka NTSV CS rate: nulliparous, term, singleton, vertex) with a Cesarean rate that has the most variation among practitioners, hospitals, regions and states. Unlike other cesarean measures, it focuses attention on the proportion of cesarean births that is affected by elective medical practices such as induction and early labor admission. Furthermore, the success (or lack thereof) of management of the first labor directly impacts the remainder of the woman's reproductive life (especially given the current high rate of repeat cesarean births).</p>	<p>California Maternal Quality Care Collaborative (CMQCC)</p> <p>Contact Information: http://cmqcc.org/</p>		Obstetrics and Gynecology
NQF 0513	<p>Title: Use of Contrast: Thorax CT</p> <p>Description: Thorax CT – Use of combined studies (with and without contrast)</p>	<p>CMS</p> <p>Contact Information: http://www.cms.hhs.gov/</p>		Radiology
NQF 0519	<p>Title: Diabetic Foot Care and Patient Education Implemented</p> <p>Description: Percent of diabetic patients for whom physician-ordered monitoring for the presence of skin lesions on the lower extremities and patient education on proper foot care were implemented during their episode of care</p>	<p>CMS</p> <p>Contact Information: http://www.cms.hhs.gov/</p>		Podiatry
NQF EC-013-08	<p>Title: Comprehensive Diabetes Care: HbA1c Control (<8.0%)</p> <p>Description: The percentage of members 18-75 years of age with diabetes (Type 1 and Type 2) who had HbA1c control (<8.0%).</p>	<p>NCQA</p> <p>Contact Information: www.ncqa.org</p>		Endocrinology, Primary Care
Not applicable	<p>Title: Hysterectomy rates</p> <p>Description:</p>			Obstetrics and Gynecology
Not applicable	<p>Title: Appropriate antibiotic use for ear infections</p> <p>Description:</p>			Pediatrics, Primary Care
Not applicable	<p>Title: Statin after Myocardial Infarction</p> <p>Description:</p>			Cardiology
Not Applicable	<p>Title: 30 day Readmission Rate</p> <p>Description:</p>			Proceduralists/Surgery
Not Applicable	<p>Title: 30 Readmission Rate following deliveries</p> <p>Description:</p>			Obstetrics and Gynecology
Not Applicable	<p>Title: Use of CT scans</p> <p>Description: Number of repeat CT scans within 60 days</p>			Pulmonology

As previously stated, we believe that there is sufficient time to implement the measures in EHR systems for 2011 through 2012. However, we recognize also that there are measures that we propose, which are in a lower state of readiness, for implementation in certified EHR's and present a higher degree of risk in terms of completion of the necessary work. We would note that the purpose of this quality reporting is to begin the process of quality benchmarking and iterative improvements in the ability of providers to benchmark themselves against their peers. As part of the public comment process, we welcome comment on not only the clinical utility of the measures we have proposed, but also their state of readiness for use in the EHR incentive programs. For those measures where electronic specifications do not currently exist, we solicit comment on how quickly electronic specifications can be developed and the period of time that might be required for effective implementation from the time the electronic specifications of final measures are posted and made available to vendors. We intend to publish electronic specifications for the proposed clinical quality measures on the CMS Web site as soon as they become available from the measure developer(s). Electronic specifications may be developed concurrently with the development of measures themselves and potentially with the NQF endorsement processes.

All of the PQRI measures included in the above clinical quality measures meet one or more of the criteria previously discussed. These measures have been through notice and comment rulemaking for PQRI. Nearly all proposed PQRI clinical quality measures are NQF endorsed. Additionally, they have broad applicability to the range of Medicare designated specialties, and the services provided by EPs who render services to Medicare and Medicaid beneficiaries and many others. Further, 9 of the 90 clinical quality measures listed above

(PQRI numbers 1, 2, 3, 5, 7, 110, 111, 112, and 113) have specifications for the electronic submission of these clinical quality measures have already been developed for the purpose of testing the electronic submission of clinical quality data extracted from an EHR for the PQRI program. The user specifications for the electronic submission of these 9 clinical quality measures for the most current PQRI program year can be found on the PQRI section of the CMS Web site at http://www.cms.hhs.gov/PQRI/20_AlternativeReportingMechanisms.asp#TopOfPage.

In terms of CMS and HHS healthcare quality priorities, clinical quality PQRI measures numbered 1, 2, 3, 5, and 7 address high priority chronic conditions, namely diabetes, coronary artery disease, and heart disease. Clinical quality PQRI measures numbered 110, 111, 112, 113, 114, 115, and 128 support prevention which is a high CMS and HHS priority. The PQRI clinical quality measure specifications for claims-based or registry-based submission of these clinical quality measures for the most current PQRI program year can be found on the PQRI section of the CMS Web site at http://www.cms.hhs.gov/PQRI/15_MeasuresCodes.asp#TopOfPage. A description of the clinical quality measure, including the clinical quality measure's numerator and denominator, can be found in the PQRI clinical quality measure specifications.

The PQRI clinical quality measures that we have included largely align with the recommendations of the HIT Standards Committee. However, we have also included certain clinical quality measures not part of PQRI that we believe are of high importance to the overall population. These clinical quality measures are IVD: Use of Aspirin or another Antithrombotic; IVD: Complete Lipid Profile; IVD: Low Density Lipoprotein (LDL-C) Control, and Blood Pressure Management. Finally, we have included an array of other measures which address important aspects of clinical quality.

In summary, we believe that this initial set of clinical quality measures is broad enough to allow for reporting for EPs and addresses high priority conditions. We recognize the importance of integrating the measures into certified EHR products for calculation of measures results, and that not all measures may be feasible for 2011 and 2012. We invite comment on the advisability of including the measures proposed for payment years 2011 and 2012. Although we recognize many other important clinical quality measures of health care provided by EPs, we anticipate expanding the set of clinical quality measures in future years and list a number of clinical quality measures for future consideration in section II.A.3.g of this preamble, on which we also invite comment.

We invite comments on our proposed clinical quality measures for EPs.

e. Clinical Quality Measures Reporting Criteria for EPs

For the 2011 and 2012 EHR reporting periods, to satisfy the requirements for reporting on clinical quality measures for Medicare under section 1848(o)(2)(A)(i) and (iii) of the Act and for Medicaid under section 1903(t)(6)(C) of the Act for the 2012 payment year, we propose to require each EP submit information on two measure groups, as shown in Table 4 and Tables 5 through 19, of this proposed rule. These are the core measures group in Table 4, and the subset of clinical measures most appropriate given the EPs specialty as described further in Tables 5 through 19 specialty group measures below. For the core measure group, in Table 4, we believe that the clinical quality measures are sufficiently general in application and of such importance to population health, we propose to require that all EPs treating Medicare and Medicaid patients in the ambulatory setting report on all of the core measures as applicable for their patients.

TABLE 4—MEASURE GROUP: CORE FOR ALL EPs, MEDICARE OR MEDICAID

Measure No.	Clinical quality measure title
PQRI 114	Title: Preventive Care and Screening: Inquiry Regarding Tobacco Use.
NQF 0028	
NQF 0013	Title: Blood pressure measurement.
NQF 0022	Title: Drugs to be avoided in the elderly: a. Patients who receive at least one drug to be avoided. b. Patients who receive at least two different drugs to be avoided.

The second required measure set for each EP is to submit information on at

least one of the sets listed in Tables 5 and 19 as specialty groups. The

specialty groups are Cardiology, Pulmonology, Endocrinology, Oncology,

Proceduralist/Surgery, Primary Care Physicians, Pediatrics, Obstetrics and Gynecology, Neurology, Psychiatry, Ophthalmology, Podiatry, Radiology, Gastroenterology, and Nephrology.

We recognize that clinical quality measures as specified by measures developers and as endorsed by the NQF are not specialty specific. Rather, the denominator of clinical quality measures and the applicability of a measure is determined by the patient population to whom the measure applies and the services rendered by the particular EP.

Nevertheless, we have grouped measures according to the types of patients commonly treated and services rendered by EPs of various specialties. We have done this for purposes similar

to measures groups used in PQRI which, however, are based on clinical conditions, rather than specialty types. The general purpose of each type of measures grouping is to have standardized sets of measures all of which must be reported by the EP in order to meet the reporting requirements. We expect to narrow down each proposed set to a required subset of 3 to 5 measures based on the availability of electronic measure specifications and comments received.

We propose to require for 2011 and 2012 that EP's will select a specialty measures group, on which to report on all applicable cases for each of the measures in the specialty group. The same specialty measures group selected for the first payment year would be

required for reporting for the second payment year. We invite comment on whether there are EPs who believe no specialty group will be applicable to them. In accordance with public comments, we will specify in the final rule which EP specialties will be exempt from selecting and reporting on a specialty measures group. EPs that are so-designated will be required to attest, to CMS or the State, to the inapplicability of any of the specialty groups and will not be required to report information on clinical quality measures from a specialty group for 2011 or 2012, though the EP will still be required to report information on all of the clinical quality measures listed in the core measure set in, Table 4, as applicable for their patients.

TABLE 5—MEASURE GROUP: CARDIOLOGY

Measure No.	Clinical quality measure title
PQRI 5	Title: Heart Failure: Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction (LVSD).
NQF 0081	
PQRI 6	Title: Coronary Artery Disease (CAD): Oral Antiplatelet Therapy Prescribed for Patients with CAD.
NQF 0067	
PQRI 7	Title: Coronary Artery Disease (CAD): Beta-Blocker Therapy for CAD Patients with Prior Myocardial Infarction (MI).
NQF 0070	
PQRI 8	Title: Heart Failure: Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD).
NQF 0083	
PQRI 118	Title: Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Patients with CAD and Diabetes and/or Left Ventricular Systolic Dysfunction (LVSD).
NQF 0066	
PQRI 128	Title: Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up.
NQF 0421	
PQRI 197	Title: Coronary Artery Disease (CAD): Drug Therapy for Lowering LDL-Cholesterol.
NQF 0074	
PQRI 200	Title: Heart Failure: Warfarin Therapy Patients with Atrial Fibrillation.
NQF 0084	
PQRI 204	Title: Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic.
NQF 0068	
Not applicable	Title: Statin after Myocardial Infarction.

TABLE 6—MEASURE GROUP: PULMONOLOGY

Measure No.	Clinical quality measure title
PQRI 52	Title: Chronic Obstructive Pulmonary Disease (COPD): Bronchodilator Therapy.
NQF 0102	
PQRI 53	Title: Asthma: Pharmacologic Therapy.
NQF 0047	
PQRI 111	Title: Preventive Care and Screening: Pneumonia Vaccination for Patients 65 Years and Older.
NQF 0043	
PQRI 114	Title: Preventive Care and Screening: Inquiry Regarding Tobacco Use.
NQF 0028	
PQRI 115	Title: Preventive Care and Screening: Advising Smokers to Quit.
NQF 0027	
NQF 0001	Title: Asthma assessment.
NQF 0036	Title: Use of appropriate medications for people with asthma.
Not applicable	Title: Use of CT scans.

TABLE 7—MEASURE GROUP: ENDOCRINOLOGY

Measure No.	Clinical quality measure title
PQRI 1	Title: Diabetes Mellitus: Hemoglobin A1c Poor Control in Diabetes Mellitus.
NQF 0059	
PQRI 2	Title: Diabetes Mellitus: Low Density Lipoprotein (LDL-C) Control in Diabetes Mellitus.
NQF 0064	

TABLE 7—MEASURE GROUP: ENDOCRINOLOGY—Continued

Measure No.	Clinical quality measure title
PQRI 3	Title: Diabetes Mellitus: High Blood Pressure Control in Diabetes Mellitus.
NQF 0061	
PQRI 117	Title: Diabetes Mellitus: Dilated Eye Exam in Diabetic Patient.
NQF 0055	
PQRI 119	Title: Diabetes Mellitus: Urine Screening for Microalbumin or Medical Attention for Nephropathy in Diabetic Patients.
NQF 0062	
PQRI 128	Title: Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up.
NQF 0421	
PQRI 204	Title: Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic.
NQF 0068	
NQF 0060	Title: Hemoglobin A1c test for pediatric patients.
Not applicable	Title: Comprehensive Diabetes Care: HbA1c Control (<8.0 percent).

TABLE 8—MEASURE GROUP: ONCOLOGY

Measure No.	Clinical quality measure title & description
PQRI 71	Title: Breast Cancer: Hormonal Therapy for Stage IC–IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer.
NQF 0387	
PQRI 72	Title: Colon Cancer: Chemotherapy for Stage III Colon Cancer Patients.
NQF 0385	
PQRI 102	Title: Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low-Risk Prostate Cancer Patients.
NQF 0389	
PQRI 112	Title: Preventive Care and Screening: Screening Mammography.
NQF 0031	
PQRI 113	Title: Preventive Care and Screening: Colorectal Cancer Screening.
NQF 0034	
NQF 0032	Title: Cervical Cancer Screening.

TABLE 9—MEASURE GROUP: PROCEDURALIST/SURGERY

Measure No.	Clinical quality measure title & description
PQRI 20	Title: Perioperative Care: Timing of Antibiotic Prophylaxis—Ordering Physician.
NQF 0270	
PQRI 21	Title: Perioperative Care: Selection of Prophylactic Antibiotic—First OR Second Generation Cephalosporin.
NQF 0268	
PQRI 22	Title: Perioperative Care: Discontinuation of Prophylactic Antibiotics (Non-Cardiac Procedures).
NQF 0271	
PQRI 23	Title: Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients).
NQF 0239	
NQF 0299	Title: Surgical Site Infection Rate.
Not Applicable	Title: 30 day Readmission Rate.

TABLE 10—MEASURE GROUP: PRIMARY CARE

Measure No.	Clinical quality measure title & description
PQRI 114	Title: Preventive Care and Screening: Inquiry Regarding Tobacco Use.
NQF 0028	
PQRI 115	Title: Preventive Care and Screening: Advising Smokers to Quit.
NQF 0027	
PQRI 202	Title: Ischemic Vascular Disease (IVD): Complete Lipid Profile.
NQF 0075	
PQRI 203	Title: Ischemic Vascular Disease (IVD): Low Density Lipoprotein (LDL-C) Control.
NQF 0075	
PQRI 204	Title: Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic.
NQF 0068	
NQF 0038	Title: Childhood Immunization Status.
PQRI 112	Title: Preventive Care and Screening: Screening Mammography.
NQF 0031	
PQRI 113	Title: Preventive Care and Screening: Colorectal Cancer Screening.
NQF 0034	
PQRI 1	Title: Diabetes Mellitus: Hemoglobin A1c Poor Control in Diabetes Mellitus.
NQF 0059	
NQF 0052	Title: Low back pain: use of imaging studies.
NQF 0018	Title: Controlling High Blood Pressure.
PQRI 128	Title: Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up.
NQF 0421	

TABLE 10—MEASURE GROUP: PRIMARY CARE—Continued

Measure No.	Clinical quality measure title & description
PQRI 65 NQF 0069	Title: Treatment for Children with Upper Respiratory Infection (URI): Avoidance of Inappropriate Use.
PQRI 66 NQF 0002	Title: Appropriate Testing for Children with Pharyngitis.
PQRI 110 NQF 0041	Title: Preventive Care and Screening: Influenza Immunization for Patients ≥ 50 Years Old.
PQRI 197 NQF 0074	Title: Coronary Artery Disease (CAD): Drug Therapy for Lowering LDL-Cholesterol.
NQF 0001 NQF 0004	Title: Asthma Assessment Title: Initiation and Engagement of Alcohol and Other Drug Dependence Treatment: (a) Initiation, (b) Engagement.
NQF 0024 NQF 0032	Title: Body Mass Index (BMI) 2 through 18 years of age. Title: Cervical Cancer Screening.
NQF 0036 NQF 0060	Title: Use of appropriate medications for people with asthma. Title: Hemoglobin A1c test for pediatric patients.
NQF 0105 NQF 0106	Title: New Episode of Depression: (a) Optimal Practitioner Contacts for Medication Management. (b) Effective Acute Phase Treatment. (c) Effective Continuation Phase Treatment.
NQF 0107 NQF 0108	Title: Diagnosis of attention deficit hyperactivity disorder (ADHD) in primary care for school age children and adolescents. Title: Management of attention deficit hyperactivity disorder (ADHD) in primary care for school age children and adolescents.
NQF 0110 Not applicable	Title: ADHD: Follow-Up Care for Children Prescribed Attention-Deficit/Hyperactivity Disorder (ADHD) Medication. Title: Bipolar Disorder and Major Depression: Appraisal for alcohol or chemical substance use.
Not applicable	Title: Comprehensive Diabetes Care: HbA1c Control (<8.0 percent).
Not applicable	Title: Appropriate antibiotic use for ear infections.

TABLE 11—MEASURE GROUP: PEDIATRICS

Measure No.	Clinical quality measure title & description
PQRI 66 NQF 0002	Title: Appropriate Testing for Children with Pharyngitis.
NQF 0060 NQF 0106	Title: Hemoglobin A1c test for pediatric patients. Title: Diagnosis of attention deficit hyperactivity disorder (ADHD) in primary care for school age children and adolescents.
NQF 0107 NQF 0108	Title: Management of attention deficit hyperactivity disorder (ADHD) in primary care for school age children and adolescents. Title: ADHD: Follow-Up Care for Children Prescribed Attention-Deficit/Hyperactivity Disorder (ADHD) Medication.
NQF 0024 NQF 0026	Title: Body Mass Index (BMI) 2 through 18 years of age. Title: Measure pair— a. Tobacco use prevention for infants, children and adolescents, b. Tobacco use cessation for infants, children and adolescents.
NQF 0038 Not applicable	Title: Childhood Immunization Status. Title: Appropriate antibiotic use for ear infections.

TABLE 12—MEASURE GROUP: OBSTETRICS AND GYNECOLOGY

Measure No.	Clinical quality measure title & description
PQRI 112 NQF 0031	Title: Preventive Care and Screening: Screening Mammography.
PQRI 128 NQF 0421	Title: Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up.
NQF 0032 NQF 0033	Title: Cervical Cancer Screening. Title: Chlamydia screening in women.
NQF 0471 NQF 0012	Title: Cesarean Rate for low-risk first birth women (aka NTSV CS rate). Title: Prenatal Screening for Human Immunodeficiency Virus (HIV).
NQF 0014 Not applicable	Title: Prenatal Anti-D Immune Globulin. Title: Hysterectomy rates.
Not applicable	Title: 30 Readmission Rate following deliveries.

TABLE 13—MEASURE GROUP: NEUROLOGY

Measure No.	Clinical quality measure title & description
PQRI 33 NQF 0241	Title: Stroke and Stroke Rehabilitation: Anticoagulant Therapy Prescribed for Atrial Fibrillation at Discharge.
PQRI 201 NQF 0073	Title: Ischemic Vascular Disease (IVD): Blood Pressure Management Control.
PQRI 202 NQF 0075	Title: Ischemic Vascular Disease (IVD): Complete Lipid Profile.
PQRI 203 NQF 0075	Title: Ischemic Vascular Disease (IVD): Low Density Lipoprotein (LDL-C) Control.
PQRI 204 NQF 0068	Title: Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic.

TABLE 14—MEASURE GROUP: PSYCHIATRY

Measure No.	Clinical quality measure title & description
PQRI 9 NQF 0105	Title: Major Depressive Disorder (MDD): Antidepressant Medication During Acute Phase for Patients with MDD.
PQRI 106 NQF 0103	Title: Major Depressive Disorder (MDD): Diagnostic Evaluation.
PQRI 107 NQF 0104	Title: Major Depressive Disorder (MDD): Suicide Risk Assessment.
NQF 0004 NQF 0105	Title: Initiation and Engagement of Alcohol and Other Drug Dependence Treatment: (a) Initiation, (b) Engagement.
NQF 0110	Title: New Episode of Depression: (a) Optimal Practitioner Contacts for Medication Management, (b) Effective Acute Phase Treatment, (c) Effective Continuation Phase Treatment.
	Title: Bipolar Disorder and Major Depression: Appraisal for alcohol or chemical substance use.

TABLE 15—MEASURE GROUP: OPHTHALMOLOGY

Measure No.	Clinical quality measure title & description
PQRI 12 NQF 0086	Title: Primary Open Angle Glaucoma (POAG): Optic Nerve Evaluation.
PQRI 18 NQF 0088	Title: Diabetic Retinopathy: Documentation of Presence or Absence of Macular Edema and Level of Severity of Retinopathy.
PQRI 19 NQF 0089	Title: Diabetic Retinopathy: Communication with the Physician Managing On-going Diabetes Care.

TABLE 16—MEASURE GROUP: PODIATRY

Measure No.	Clinical quality measure title & description
PQRI 127 NQF 0416	Title: Diabetes Mellitus: Diabetic Foot and Ankle Care, Ulcer Prevention—Evaluation of Footwear.
PQRI 163 NQF 0056	Title: Diabetes Mellitus: Foot Exam.
NQF 0519	Title: Diabetic Foot Care and Patient Education Implemented.

TABLE 17—MEASURE GROUP: RADIOLOGY

Measure No.	Clinical quality measure title & description
PQRI 10 NQF 0246	Title: Stroke and Stroke Rehabilitation: Computed Tomography (CT) or Magnetic Resonance Imaging (MRI) Reports.
PQRI 195 NQF 0507	Title: Stenosis Measurement in Carotid Imaging Studies.
PQRI 145 NQF 0510	Title: Radiology: Exposure Time Reported for Procedures Using Fluoroscopy.
PQRI 146 NQF 0508	Title: Radiology: Inappropriate Use of “Probably Benign” Assessment Category in Mammography Screening.
PQRI 147 NQF 0511	Title: Nuclear Medicine: Correlation with Existing Imaging Studies for All Patients Undergoing Bone Scintigraphy.
NQF 0052	Title: Low back pain: use of imaging studies.
NQF 0513	Title: Use of Contrast: Thorax CT.

TABLE 18—MEASURE GROUP: GASTROENTEROLOGY

Measure No.	Clinical quality measure title & description
PQRI 86 NQF 0397	Title: Hepatitis C: Antiviral Treatment Prescribed.
PQRI 89 NQF 0401	Title: Hepatitis C: Counseling Regarding Risk of Alcohol Consumption.
PQRI 113 NQF 0034	Title: Preventive Care and Screening: Colorectal Cancer Screening.
PQRI 183 NQF 0399	Title: Hepatitis C: Hepatitis A Vaccination in Patients with HCV.
PQRI 184 NQF 0400	Title: Hepatitis C: Hepatitis B Vaccination in Patients with HCV.
PQRI 185 AQA adopted	Title: Endoscopy & Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps—Avoidance of Inappropriate Use.

TABLE 19—MEASURE GROUP: NEPHROLOGY

Measure No.	Clinical quality measure title & description
PQRI 81 NQF 0323	Title: End Stage Renal Disease (ESRD): Plan of Care for Inadequate Hemodialysis in ESRD Patients.
PQRI 82 NQF 0321	Title: End Stage Renal Disease (ESRD): Plan of Care for Inadequate Peritoneal Dialysis.
PQRI 121 AQA adopted	Title: Chronic Kidney Disease (CKD): Laboratory Testing (Calcium, Phosphorus, Intact Parathyroid Hormone (iPTH) and Lipid Profile).
PQRI 122 AQA adopted	Title: Chronic Kidney Disease (CKD): Blood Pressure Management.
PQRI 123 AQA adopted	Title: Chronic Kidney Disease (CKD): Plan of Care—Elevated Hemoglobin for Patients Receiving Erythropoiesis-Stimulating Agents (ESA).
PQRI 153 AQA adopted	Title: Chronic Kidney Disease (CKD): Referral for Arteriovenous (AV) Fistula.

With the inclusion of measures applicable to targeting children and adolescents and the wide applicability of the measures like Blood Pressure Management, we believe this core set of clinical quality measures and specialty measures is broad enough to enable reporting by all EPs. However, if the public believes that other EPs would not have sufficient patients in the denominator of these core measures, we encourage commenters to identify the EPs in question and propose specific remedies.

Although we do not propose to require clinical quality measure reporting electronically until 2012, we propose to begin clinical quality reporting through attestation in the 2011 payment year. We solicit comment on whether it may be more appropriate to defer some or all clinical quality reporting until the 2012 payment year. If reporting on some but not all measures in 2011 is feasible, we solicit comment on which key measures should be chosen for 2011 and which should be deferred until 2012 and why.

We further propose that starting in payment year 2012, in addition to meeting requirements for measures on meaningful EHR use and other requirements, EPs would be required to electronically submit this quality reporting information directly to CMS and States using certified EHR technology. We encourage comments on these reporting criteria, particularly on the requirement that all EPs—would report on the set of “core measures.” We are also interested in comments as to whether some Medicare or Medicaid EPs may not be able to meet the proposed reporting requirements, why that might be the case, and whether commenters believe other alternative options are preferable.

f. Proposed Clinical Quality Measures for Electronic Submission by Eligible Hospitals

Based on the considerations for clinical quality measures previously discussed in this proposed rule, we propose that eligible hospitals will be required to report summary data to CMS on the set of clinical quality measures

identified in Table 20 starting in the 2011 payment year. We further propose that for the 2012 payment year, hospitals will be required to submit these measures to CMS electronically using certified EHR technology on a set of clinical quality measures identified in Table 20, which would be sufficient to meet the requirements for both the Medicare and the Medicaid EHR incentive (for hospitals eligible for both incentive programs), with respect to the requirement to report clinical quality measures. For hospitals eligible for only the Medicaid EHR incentive program, such reporting will be to States. For eligible hospitals to which the measures in Table 20 do not apply to their patient population, hospitals have the option to select clinical quality measures identified in Table 21 to meet the requirements for the reporting of clinical quality measures for the Medicaid program incentive. Tables 20 and 21, convey the clinical quality measure's title, number, owner/developer and contact information, and a link to existing electronic specifications where applicable.

TABLE 20—PROPOSED CLINICAL QUALITY MEASURES FOR ELECTRONIC SUBMISSION BY ELIGIBLE HOSPITALS FOR PAYMENT YEAR 2011–2012

Measure No. identifier	Measure title, description & measure developer	Electronic measure specifications information
ED-1	Title: Emergency Department Throughput—admitted patients. Median time from ED arrival to ED departure for admitted patients.	http://www.hitsp.org/ConstructSet_Details.aspx?&PrefixAlpha=5&PrefixNumeric=906 .
NQF 0495	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. Measure Developer: CMS/Oklahoma Foundation for Medical Quality (OFMQC).	
ED-2	Title: Emergency Department Throughput—admitted patients. Admission decision time to ED departure time for admitted patients.	
NQF 0497	Description: Median time from admit decision time to time of departure from the emergency department of emergency department patients admitted to inpatient status. Measure Developer: CMS/OFMQ.	http://www.hitsp.org/ConstructSet_Details.aspx?&PrefixAlpha=5&PrefixNumeric=906 .
ED-3	Title: Emergency Department Throughput—discharged patients. Median Time from ED Arrival to ED Departure for Discharged ED Patients.	
NQF 0496	Description: Median Time from ED arrival to time of departure from the ED for patients discharged from the ED. Measure Developer: CMS/OFMQ.	
Stroke-2	Title: Ischemic stroke—Discharge on anti-thrombotics	http://www.hitsp.org/ConstructSet_Details.aspx?&PrefixAlpha=5&PrefixNumeric=906 .
NQF 0435	Description: Ischemic stroke patients prescribed antithrombotic therapy at hospital discharge. Measure Developer: The Joint Commission.	
Stroke-3	Title: Ischemic stroke—Anticoagulation for A-fib/flutter	
NQF 0436	Description: Ischemic stroke patients with atrial fibrillation/flutter who are prescribed anticoagulation therapy at hospital discharge. Measure Developer: The Joint Commission.	http://www.hitsp.org/ConstructSet_Details.aspx?&PrefixAlpha=5&PrefixNumeric=906 .
Stroke-4	Title: Ischemic stroke—Thrombolytic therapy for patients arriving within 2 hours of symptom onset.	
NQF 0437	Description: Acute ischemic stroke patients who arrive at this hospital within 2 hours of time last known well and for whom IV t-PA was initiated at this hospital within 3 hours of time last known well. Measure Developer: The Joint Commission.	
Stroke-5	Title: Ischemic or hemorrhagic stroke—Antithrombotic therapy by day 2	http://www.hitsp.org/ConstructSet_Details.aspx?&PrefixAlpha=5&PrefixNumeric=906 .
NQF 0438	Description: Ischemic stroke patients administered antithrombotic therapy by the end of hospital day 2. Measure Developer: The Joint Commission.	
Stroke-6	Title: Ischemic stroke—Discharge on statins	
NQF 0439	Description: Ischemic stroke patients with LDL > 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. Measure Developer: The Joint Commission.	http://www.hitsp.org/ConstructSet_Details.aspx?&PrefixAlpha=5&PrefixNumeric=906 .
Stroke-8	Title: Ischemic or hemorrhagic stroke—Stroke education	

TABLE 20—PROPOSED CLINICAL QUALITY MEASURES FOR ELECTRONIC SUBMISSION BY ELIGIBLE HOSPITALS FOR PAYMENT YEAR 2011–2012—Continued

Measure No. identifier	Measure title, description & measure developer	Electronic measure specifications information
NQF 0440	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. Measure Developer: The Joint Commission.	http://www.hitsp.org/ConstructSet_Details.aspx?&PrefixAlpha=5&PrefixNumeric=906 .
Stroke-10	Title: Ischemic or hemorrhagic stroke—Rehabilitation assessment	
NQF 0441	Description: Ischemic or hemorrhagic stroke patients who were assessed for rehabilitation services. Measure Developer: The Joint Commission.	http://www.hitsp.org/ConstructSet_Details.aspx?&PrefixAlpha=5&PrefixNumeric=906 .
VTE-1	Title: VTE prophylaxis within 24 hours of arrival	
NQF 0371	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. Measure Developer: The Joint Commission.	http://www.hitsp.org/ConstructSet_Details.aspx?&PrefixAlpha=5&PrefixNumeric=906 .
VTE-2	Title: ICU VTE prophylaxis	
NQF 0372	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). Measure Developer: The Joint Commission.	http://www.hitsp.org/ConstructSet_Details.aspx?&PrefixAlpha=5&PrefixNumeric=906 .
VTE-3	Title: Anticoagulation overlap therapy	
NQF 0373	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. Measure Developer: The Joint Commission.	http://www.hitsp.org/ConstructSet_Details.aspx?&PrefixAlpha=5&PrefixNumeric=906 .
VTE-4	Title: Platelet monitoring on unfractionated heparin	
NQF 0374	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. Measure Developer: The Joint Commission.	http://www.hitsp.org/ConstructSet_Details.aspx?&PrefixAlpha=5&PrefixNumeric=906 .
VTE-5	Title: VTE discharge instructions	
NQF 0375	Description: This measure assesses the number of patients diagnosed with confirmed VTE that are discharged to home, to home with home health, home hospice or discharged/transferred to court/law enforcement 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.	

TABLE 20—PROPOSED CLINICAL QUALITY MEASURES FOR ELECTRONIC SUBMISSION BY ELIGIBLE HOSPITALS FOR PAYMENT YEAR 2011–2012—Continued

Measure No. identifier	Measure title, description & measure developer	Electronic measure specifications information
VTE-6	Measure Developer: The Joint Commission. Title: Incidence of potentially preventable VTE	http://www.hitsp.org/ ConstructSet_Details. aspx?&Prefix Alpha=5&Prefix Numeric=906.
NQF 0376	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. Measure Developer: The Joint Commission.	
RHQDAPU AMI-8a	Title: Primary PCI Received Within 90 Minutes of Hospital Arrival.	
NQF 0163	Description: Acute myocardial infarction (AMI) patients with ST-segment elevation or LBBB on the ECG closest to arrival time receiving primary PCI during the hospital stay with a time from hospital arrival to PCI of 90 minutes or less. Measure Developer: CMS/OFMQ.	
RHQDAPU PN-3b	Title: Blood Cultures Performed in the Emergency Department Prior to Initial Antibiotic Received in Hospital.	
NQF 0148	Description: Pneumonia patients whose initial emergency room blood culture specimen was collected prior to first hospital dose of antibiotics. This measure focuses on the treatment provided to Emergency Department patients prior to admission orders. Measure Developer: CMS/OFMQ.	
RHQDAPU AMI-2	Title: Aspirin Prescribed at Discharge.	
NQF 0142	Description: Acute myocardial infarction (AMI) patients who are prescribed aspirin at hospital discharge. Measure Developer: CMS/OFMQ.	
RHQDAPU AMI-3	Title: Angiotensin Converting Enzyme Inhibitor (ACEI) or Angiotensin Receptor Blocker (ARB) for Left Ventricular Systolic Dysfunction (LVSD).	
NQF 0137	Description: Acute myocardial infarction (AMI) patients with left ventricular systolic dysfunction (LVSD) 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. Measure Developer: CMS/OFMQ.	
RHQDAPU AMI-5	Title: Beta-Blocker Prescribed at Discharge.	
NQF 0160	Description: Acute myocardial infarction (AMI) patients who are prescribed a betablocker at hospital discharge. Measure Developer: CMS/OFMQ.	
RHQDAPU AMI-READ	Title & Description: Hospital Specific 30 day Risk-Standardized Readmission Rate following AMI admission.	
NQF 0505	Measure Developer: CMS.	
Not applicable	Title: Hospital Specific 30 day Rate following AMI admission.	
RHQDAPU HF-READ	Title & Description: Hospital Specific 30 day Risk-Standardized Readmission Rate following Heart Failure admission.	
NQF 0330	Measure Developer: CMS/OFMQ.	
Not applicable	Title: Hospital Specific 30 day Rate following Heart Failure admission.	
RHQDAPU PNE-READ	Title & Description: Hospital Specific 30 day Risk-Standardized Readmission Rate following Pneumonia admission.	
NQF 0506	Measure Developer: CMS.	
Not applicable	Title: Hospital Specific 30 day Rate following Pneumonia admission.	
NQF 0528	Title: Infection SCIP Inf-2 Prophylactic antibiotics consistent with current recommendations. Description: Surgical patients who received prophylactic antibiotics consistent with current guidelines (specific to each type of surgical procedure). Measure Developer: CMS/OFMQ.	
NQF 0302	Title: Ventilator Bundle. Description: Percentage of intensive care unit patients on mechanical ventilation at time of survey for whom all four elements of the ventilator bundle are documented and in place. The ventilator bundle elements are: • Head of bed (HOB) elevation 30 degrees or greater (unless medically contraindicated); noted on 2 different shifts within a 24 hour period.	

TABLE 20—PROPOSED CLINICAL QUALITY MEASURES FOR ELECTRONIC SUBMISSION BY ELIGIBLE HOSPITALS FOR PAYMENT YEAR 2011–2012—Continued

Measure No. identifier	Measure title, description & measure developer	Electronic measure specifications information
NQF 0298	<ul style="list-style-type: none"> Daily “sedation interruption” and daily assessment of readiness to extubate; process includes interrupting sedation until patient follow commands and patient is assessed for discontinuation of mechanical ventilation; Parameters of discontinuation include: resolution of reason for intubation; inspired oxygen content roughly 40%; assessment of patients ability to defend airway after extubation due to heavy sedation; minute ventilation less than equal to 15 liters/minute; and respiratory rate/tidal volume less than or equal to 105/min/L (RR/TV < 105). SUD (peptic ulcer disease) prophylaxis DVT (deep venous thrombosis) prophylaxis. <p>Measure Developer: IHI. Title: Central Line Bundle Compliance. Description: Percentage of intensive care patients with central lines for whom all elements of the central line bundle are documented and in place. The central line bundle elements include:</p> <ul style="list-style-type: none"> Hand hygiene. Maximal barrier precautions upon insertion. Chlorhexidine skin antisepsis. Optimal catheter site selection, with subclavian vein as the preferred site for non-tunneled catheters in patients 18 years and older. Daily review of line necessity with prompt removal of unnecessary lines. 	
NQF 0140	<p>Measure Developer: IHI. Title: Ventilator-associated pneumonia for ICU and high-risk nursery (HRN) patients. Description: Percentage of ICU and HRN patients who over a certain amount of days have ventilator-associated pneumonia.</p>	
NQF 0138	<p>Measure Developer: CDC. Title: Urinary catheter-associated urinary tract infection for intensive care unit (ICU) patients. Description: Percentage of intensive care unit patients with urinary catheter-associated urinary tract infections.</p>	
NQF 0139	<p>Measure Developer: CDC. Title: Central line catheter-associated blood stream infection rate for ICU and high-risk nursery (HRN) patients. Description: Percentage of ICU and high-risk nursery patients, who over a certain amount of days acquired a central line catheter-associated blood stream infections over a specified amount of line-days.</p>	
NQF 0329	<p>Measure Developer: CDC. Title: All-Cause Readmission Index (risk adjusted). Description: Overall inpatient 30-day hospital readmission rate.</p>	
Not applicable	<p>Measure Developer: United Health Group. Title: All-Cause Readmission Index. Description: Overall inpatient 30-day hospital readmission rate.</p>	

TABLE 21—PROPOSED ALTERNATIVE MEDICAID CLINICAL QUALITY MEASURES FOR MEDICAID ELIGIBLE HOSPITALS

NQF No.	Measure title, description & measure developer	Electronic measure specifications information
0341	<p>Title: PICU Pain Assessment on Admission. Description: Percentage of PICU patients receiving:</p> <ol style="list-style-type: none"> Pain assessment on admission. Periodic pain assessment. <p>Measure Developer: Vermont Oxford Network.</p>	
0348	<p>Title: Iatrogenic pneumothorax in non-neonates (pediatric up to 17 years of age). Description: Percent of medical and surgical discharges, age under 18 years, with ICD–9–CM code of iatrogenic pneumothorax in any secondary diagnosis field. Measure Developer: AHRQ.</p>	
0362	<p>Title: Foreign body left after procedure, age under 18 years. Description: Discharges with foreign body accidentally left in during procedure per 1,000 discharges. Measure Developer: AHRQ.</p>	
0151	<p>Title: Pneumonia Care PNE–5c Antibiotic. Description: Percentage of pneumonia patients 18 years of age and older who receive their first dose of antibiotics within 6 hours after arrival at the hospital. Measure Developer: CMS/OFMQ.</p>	
0147	<p>Title: Pneumonia Care PN–6 Antibiotic selection. Description: Percentage of pneumonia patients 18 years of age or older selected for initial receipts of antibiotics for community-acquired pneumonia (CAP).</p>	

TABLE 21—PROPOSED ALTERNATIVE MEDICAID CLINICAL QUALITY MEASURES FOR MEDICAID ELIGIBLE HOSPITALS—Continued

NQF No.	Measure title, description & measure developer	Electronic measure specifications information
0356	Measure Developer: CMS/OFMQ. Title: Pneumonia Care PN-3a Blood culture. Description: Percent of pneumonia patients, age 18 years or older, transferred or admitted to the ICU within 24 hours of hospital arrival who had blood cultures performed within 24 hours prior to or 24 hours after arrival at the hospital.	
0527	Measure Developer: CMS/OFMQ. Title: Infection SCIP Inf-1 Prophylactic antibiotic received within 1 hour prior to surgical incision. Description: Surgical patients with prophylactic antibiotics initiated within 1 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.	
0529	Measure Developer: CMS/OFMQ. Title: Infection 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 <i>Anesthesia End Time</i> . Measure Developer: CMS/OFMQ.	

We have included in the hospital measures set several clinical quality measures which have undergone development of electronic specifications. These clinical quality measures have been developed for future RHQDAPU consideration. The electronic specifications were developed through an interagency agreement with ONC to develop interoperable standards for EHR submission of the ED throughput, stroke, and VTE clinical quality measures on Table 20, to be determined by a future rulemaking document provided by ONC. We also have planned to test the submission of these clinical quality measures in Medicare (see 74 FR 43893). The specifications for the RHQDAPU clinical quality measures for eligible hospitals that are being used for testing EHR-based submission of these clinical quality measures can be found at http://www.hitsp.org/ConstructSet_Details.aspx?&PrefixAlpha=5&PrefixNumeric=906. A description of the clinical quality measure, including the clinical quality measure's numerator and denominator, can be found here as well. Other measures are currently in the RHQDAPU program or are measures of importance for measuring or preventing adverse outcomes. In addition to Risk Standardized readmission clinical quality measures, we have proposed Readmission rates to be reported which are not risk adjusted. We have also reviewed the recommendations of the HIT Standards Committee that apply to hospitals which include Atrial Fibrillation Receiving Anticoagulation

Therapy. We note that Atrial Fibrillation Receiving Anticoagulation Therapy is one of the clinical quality measures included on Table 20, identified in the table as Stroke-3. We note that we have not included the HIT Standards Committee recommended clinical quality measure on surgery patients who received VTE prophylaxis within 24 hours period to surgery to 24 hours after surgery end time because it is a current clinical quality measure collected in the RHQDAPU program through chart abstraction for all applicable patients (SCIP-VTE-2). The VTE-2 clinical quality measure in Table 20 is a parallel clinical quality measure to SCIP-VTE-2, includes non-surgical patients, and is a more feasible to implement because the electronic specifications have been completed. We have however added SCIP-VTE-2 for future consideration.

To satisfy the requirements of reporting on clinical quality measures under sections 1886(n)(3)(A)(iii) and 1903(t)(6)(C) of the Act for the 2011–2012 payment year, we propose to require eligible hospitals to report on all EHR incentive clinical quality measures for which they have applicable cases, without regard to payer. Medicare eligible hospitals, who are also participating in the Medicaid EHR incentive program, will also be required to report on all Medicaid clinical quality measures for which the eligible hospital has applicable cases. To demonstrate that it is an eligible meaningful EHR user, the eligible hospital is required to electronically submit information on each clinical quality measures for each patient to whom the clinical quality

measure applies, regardless of payer, discharged from the hospital during the EHR reporting period and for whom the clinical quality measure is applicable. Although we do not propose to require clinical quality reporting electronically until 2012, we propose to begin clinical quality reporting though attestation in the 2011 payment year. We solicit comment on whether it may be more appropriate to defer some or all clinical quality reporting until the 2012 payment year. If reporting on some but not all measures in 2011 is feasible, we solicit comment on which key measures should be chosen for 2011 and which should be deferred until 2012 and why.

We invite comments on these proposed clinical quality measures for eligible hospitals and our proposed timelines to post specification documents for these clinical quality measures to the CMS Web site.

g. Request for Public Comment on Potential Measures for EPs and Eligible Hospitals in 2013 Payment Year and Subsequent Years

We expect that the number of clinical quality measures for which EPs and eligible hospitals will be able to electronically submit information will rapidly expand in 2013 and beyond.

We plan to consider measures from the 2010 PQRI program. These clinical quality measures can be found at http://www.cms.hhs.gov/PQRI/05_StatuteRegulationsProgramInstructions.asp

For future considerations of clinical quality measures for 2013 and beyond for eligible hospitals, we will also

consider other clinical quality measures from the RHQDAPU program which are identified in the FY 2010 IPPS final rule (74 FR 43868 through 43882). We invite comments on inclusion of clinical quality measures for the 2013 and beyond HITECH Act Medicare and Medicaid incentive program, based on Stage 2 and Stage 3 meaningful use criteria.

For the 2013 payment year, we are considering expanding the Medicaid EHR incentive programs clinical quality measure set for EPs and eligible hospitals to include clinical quality measures that address the following clinical areas, to address quality of care for additional patient populations, and facilitate alignment with Medicaid and CHIP programs:

- Additional pediatrics measures (such as completed growth charts, electronic prescriptions with weight-based dosing support and documentation of newborn screening).
- Long-term care measures.
- Additional obstetrics measure.
- Dental care/oral health measures.
- Additional mental health and substance abuse measures.

The above lists do not constitute a comprehensive list of all clinical quality measures that may be considered. Specific measures for payment years 2013 and beyond will be addressed by CMS in future notice and comment rulemaking. To assist us in identifying potential clinical quality measures for future consideration for years 2013 and beyond, we welcome comments on the potential topics and/or clinical quality measures listed above as well as suggestions for additional clinical quality measure topics and/or specific clinical quality measures.

h. Proposed Reporting Method for Clinical Quality Measures for 2011 and 2012 Payment Year

(1) Reporting Method for 2011 Payment Year

As we previously discussed, we propose to use attestation as a means for EPs and eligible hospitals, for purposes of the Medicare incentive program, to demonstrate the meaningful use requirement for the calculation and submission of clinical quality measure results to CMS.

Specifically, for 2011, we propose to require that Medicare EPs and hospitals attest to the use of a certified EHR system to capture the data elements and calculate the results for the applicable clinical quality measures.

We further propose to require that Medicare EPs and eligible hospitals attest to the accuracy and completeness

of the numerators, denominators, and exclusions submitted for each of the applicable measures, and report the results to CMS for all applicable patients.

Attestation will utilize the same system for other attestation for meaningful use, and we propose to require for Medicare EPs that they attest to the following:

- The information submitted with respect to clinical quality measures was generated as output of an identified certified electronic health record.
- The information submitted is accurate to the best of the knowledge and belief of the EP.
- The information submitted includes information on all patients to whom the clinical quality measure applies.
- The NPI and TIN of the EP submitting the information, and the specialty group of clinical quality measures that are being submitted.
- For an EP who is exempt from reporting each of the core measures, an attestation that one or more of the core measures do not apply to the scope of practice of the EP.
- For an EP who is exempt from reporting on a specialty group, an attestation that none of the specialty groups applies to the scope of practice of the EP.
- For an EP who does report on a specialty group, but is exempt from reporting on each of the clinical quality measures in the group, an attestation that the clinical quality measures not reported do not apply to any patients treated by the EP.
- The numerators, denominators, and exclusions for each clinical quality measure result reported, providing separate information for each clinical quality measure including the numerators, denominators, and exclusions for all patients irrespective third party payer or lack thereof; for Medicare FFS patients; for Medicare Advantage patients; and for Medicaid patients.

- The beginning and end dates for which the numerators, denominators, and exclusions apply.

For eligible hospitals, we propose to require that they attest to the following:

- The information submitted with respect to clinical quality measures was generated as output from an identified certified EHR.
- The information submitted to the knowledge and belief of the official submitting on behalf of the eligible hospital.
- The information submitted includes information on all patients to whom the measure applies.

- The identifying information for the eligible hospital.

- For eligible hospitals that do not report one or more measures an attestation that the clinical quality measures not reported do not apply to any patients treated by the eligible hospital during the reporting period.

- The numerators, denominators, and exclusions for each clinical quality measure result reported, providing separate information for each clinical quality measure including the numerators, denominators, and exclusions for all patients irrespective third party payer or lack thereof; for Medicare FFS patients; for Medicare Advantage patients; and for Medicaid patients.

- The beginning and end dates for which the numerators, denominators, and exclusions apply.

(2) Reporting Method for 2012

In accordance with sections 1848(o)(2)(A)(iii) and 1886(n)(3)(A)(iii) of the Act, an EP or eligible hospital, respectively, must submit summary information (that is, information that is not personally identifiable) on the clinical quality measures selected by the Secretary using certified EHR technology in order to demonstrate their meaningful use of certified EHR technology. Additionally, for the 2012 payment year, we propose that EPs and eligible hospitals be required to electronically submit the summary information for a selected clinical quality measure from those listed in Tables 3 through 21 using certified EHR technology as defined in section II.A.1.a of this proposed rule for the Medicare and Medicaid incentives. The required Medicare incentive information will be identified in the measures specifications, which we intend will be on our Web site 9 months before the start of the payment year. For Medicaid, EPs and hospitals eligible only for the Medicaid EHR incentive program must report their clinical quality measures data to States. States will propose to CMS how they plan to accept and validate Medicaid providers' clinical quality measures data in their State Medicaid HIT Plans, subject to CMS review and approval, as described in section II.D.7. of this proposed rule.

Sections 1848(o)(A)(2)(iii) and 1886(n)(3)(A)(iii) of the Act broadly state that as a condition of demonstrating meaningful use of certified EHR technology, an EP, CAH or eligible hospital must "submit information" for the EHR reporting period on the clinical quality or other measures selected by the Secretary "in a form and manner specified by the

Secretary.” This language does not limit us to collecting only that information pertaining to Medicare and Medicaid beneficiaries. Therefore, we believe that we have the authority to collect summarized clinical quality measures selected by the Secretary, with respect to all patients to whom the clinical quality measure applies, treated by the EP or eligible hospital. We believe that it is necessary for the EP or eligible hospital to report on all cases to which a clinical quality measure applies in order to accurately assess the quality of care rendered by the particular EP or eligible hospital generally. Otherwise it would only be possible to evaluate the care being rendered for a portion of patients and lessen the ability to improve quality generally. We solicit comments on the impact of requiring the submission of clinical quality measures data on all patients, not just Medicare and Medicaid beneficiaries.

Sections 1848(o)(2)(B)(iii) and 1886(n)(3)(B)(iii) of the Act requires that in selecting clinical quality measures, the Secretary shall seek to avoid redundant or duplicative reporting otherwise required, including reporting under section 1848(k)(2)(C) of the Act (the PQRI program) and eligible reporting under section 1886(b)(3)(B)(viii) of the Act (RHQDAPU program). We interpret “redundant or duplicative reporting” to mean requiring the reporting of data on the same clinical quality measure separately for two or more quality reporting programs under Medicare. Similarly, we seek to align clinical quality measure reporting activities under CHIPRA with those proposed here, to avoid duplication of reporting and to strengthen the quality reporting infrastructure more broadly. Therefore, when a clinical quality measure is included in more than one quality reporting incentive program, we will seek to avoid requiring EPs and eligible hospitals to report the same clinical quality measure under separate programs. In instances in which a particular clinical quality measure is included in the Medicare EHR incentive program and another Medicare quality reporting incentive program, an EP or eligible hospital would only need to report the measure under the Medicare EHR incentive program, and the reporting of such clinical quality measure using certified EHR technology would be considered as the EP or eligible hospitals having satisfied the parallel reporting requirement under all other applicable Medicare programs. With respect to any clinical quality measures that may be included in the

measure sets for both the Medicare EHR Incentive Programs for EPs and the PQRI, we note that there is no existing statutory authority to make PQRI incentive payments for services furnished in 2011 and subsequent years.

We propose that Medicare EPs and eligible hospitals would be required to report the required clinical quality measures information electronically using certified EHR technology via one of three methods. The primary method would require the EP or eligible hospital to log into a CMS-designated portal. Once the EP or eligible hospital has logged into the portal, they would be required to submit, through an upload process, data payload based on specified structures, such as Clinical Data Architecture (CDA), and accompanying templates produced as output from their certified EHR technology.

As an alternative to this data submission method, we propose to permit Medicare EPs and eligible hospitals to submit the required clinical quality measures data using certified EHR technology through Health Information Exchange (HIE)/Health Information Organization (HIO). This alternative data submission method would be dependent on the Secretary’s ability to collect data through a HIE/HIO network and would require the EP or eligible hospital who chooses to submit data via an HIE/HIO network to be a participating member of the HIE/HIO network. Medicare EPs and eligible hospitals would be required to submit their data payload based on specified structures or profiles, such as Clinical Data Architecture (CDA), and accompanying templates. The EP’s or eligible hospital’s data payload should be an output from their respective certified EHR products, in the form and manner specified from their HIE/HIO adopted architecture into the CMS HIE/HIO adopted architecture.

As another potential alternative, we propose to accept submission through registries dependent upon the development of the necessary capacity and infrastructure to do so using certified EHRs.

We intend to post the technical requirements for portal submission and the alternative HIE/HIO submission, the HIE/HIO participating member definition, and other specifications for submission on our Web site for Medicare EPs on or before July 1, 2011 and for Medicare eligible hospitals on or before April 1, 2011 for EHR adoption and incorporation and to accommodate EHR vendors.

We invite comments on our three proposed clinical quality measures data submission methodologies as they

pertain to CMS for Medicare and to States for Medicaid.

i. Alternative Reporting Methods for Clinical Quality Measures

There are several alternative reporting methods we considered to create a dataset of provider-submitted summary data. One such alternative is the development of a distributed network of EHRs where health information is retained locally in individual EP or eligible hospital EHRs and only summary reports are submitted to CMS. Another alternative is the creation of databases of patient-level EHR data stored at the state or regional level. We invite comment on our proposed approach, as well as our two alternatives. We also invite comment on all other alternative reporting methods.

j. Proposed Reporting Criteria for EPs and Eligible Hospitals

Sections 1848(o)(A)(2)(iii) and 1886(n)(3)(A)(iii) of the Act state that to demonstrate meaningful use of certified EHR technology for an EHR reporting period, an EP and eligible hospital must submit information “for such period” on the clinical quality measures and other measures selected by the Secretary. We therefore propose that for 2011 and 2012, the reporting period for the clinical quality measures selected by the Secretary be the EHR reporting period as previously defined in section II.A.1.e. of this proposed rule.

Another alternative we considered was a fixed reporting period of four quarterly reporting periods, or 2, 6-month reporting periods. In terms of practice and precedent for other Medicare clinical quality measure reporting programs, all submit data to us at specific reporting intervals.

We invite industry and interested stakeholder comments on our proposal, especially those who may feel that a fixed period would be more advantageous.

k. Addressing Dually Eligible Medicare/Medicaid Beneficiaries Under HITECH

Since the EHR incentives are based on Medicare or Medicaid EPs choosing one program or the other, we are concerned that the Medicare and Medicaid incentive programs address the HIT needs of dually eligible program beneficiaries. Since this population requires special coordination between the State and Federal government, we intend to engage in new efforts to promote Medicare health information exchange with States, as well as look for other new ways to meet the care management objectives of this population through HIT. As such, we

are requesting comments on potential measures to reach our goal.

4. Demonstration of Meaningful Use

Section 1848(o)(3)(C) of the Act, as added by section 4101(a) of the HITECH Act, requires that as a condition of eligibility for the incentive payment, an EP must demonstrate meaningful use of certified EHR technology (other than the reporting on clinical quality and other measures) as discussed in section II.A.3 of this proposed rule in the manner specified by the Secretary, which may include the following: An attestation, the submission of claims with appropriate coding, a survey response, reporting of clinical quality or other measures, or other means. Similarly, section 1886(n)(3)(c) of the Act, as added by section 4102(a) of the HITECH Act, requires that hospitals seeking the incentive payment demonstrate meaningful use of certified EHR technology in the manner specified by the Secretary. Section 1903(t)(6)(C)(i)(II) of the Act, as added by section 4201(a)(2) under the HITECH Act, states that a Medicaid EP or eligible hospital must demonstrate meaningful use through a “means that is approved by the State and acceptable to the Secretary.” In addition, pursuant to section 1903(t)(9) of the Act, a State must demonstrate to the satisfaction of the Secretary that the State is conducting adequate oversight, including the routine tracking of meaningful use attestations and reporting mechanisms.

a. Common Methods of Demonstration in Medicare and Medicaid

We propose to create a common method for demonstrating meaningful use in both the Medicare and Medicaid EHR incentive programs, for the same reasons we have proposed a uniform definition of meaningful use. 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 two parts, as discussed below. States seeking to modify or propose alternative demonstration methods must submit the proposed methods for prior CMS approval. This process is discussed more fully in Section II.D.7.b.2.c. of this proposed rule.

b. Methods for Demonstration of the Stage 1 Criteria of Meaningful Use

We are proposing at § 495.8 that for CY 2011 and FY 2011, EPs and eligible hospitals demonstrate that they satisfy each of the proposed meaningful use objectives specified in § 495.6 through

attestation. For payment years beginning in CY and FY 2012 and subsequent years, we are proposing at § 495.8 that EPs and eligible hospitals demonstrate that they satisfy each of the proposed meaningful use objectives other than “Submitting quality measures to CMS or the States” through attestation, and demonstrate that they satisfy the objective “Submitting quality measure to CMS or the States” through electronic reporting of clinical quality measures to CMS or the States, as specified in section II.A.3 of this proposed rule. Specifically, we propose that EPs and eligible hospitals provide attestation through a secure mechanism, such as through claims based reporting or an online portal. We propose that an EP or eligible hospital would through a one-time attestation following the completion of the EHR reporting period for a given payment year identify the certified EHR technology they are utilizing and the results of their performance on all the measures associated with the objectives of meaningful use. We chose to propose attestation through a secure mechanism because we do not believe that HIT will advance enough from its current state to allow for more automated and/or documented options of demonstrating meaningful use. 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 non clinical and documented participation in HIE. The first example is to the move from attestation for clinical quality measures to direct reporting in 2012 and subsequent years for EPs and eligible hospitals. As HIT advances we expect to move more of the objectives away from being demonstrated through attestation. However, given the current state of HIT, we believe that imposing such demonstration requirements for 2011 would pose significant barriers to participation in the EHR incentive programs.

We believe that the means by which EPs and eligible hospitals demonstrate meaningful use should work for all provider types. We also believe that uniform means of demonstration for EPs and eligible hospitals are preferable and that a greater burden should not be placed on one or the other. In addition, we do not believe that demonstration of meaningful use should require use of certified EHR technology beyond the capabilities certified to be determined by a future rulemaking document provided by ONC.

In addition to requiring electronic reporting of clinical quality measures in

2012 in Medicare and Medicaid, we also propose 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 do not propose to require any EP or eligible hospital to participate in this testing in either 2011 or 2012 in order to receive an incentive payment. However, in order to make progress towards our goal of meaningful use being demonstrated through the electronic exchange of information we encourage States to explore the available options. The state of electronic exchange varies widely across the country and is dependent on numerous Federal, State, local, non-profit and for-profit initiatives. Given this high state of flux, CMS and/or the States would have to issue considerable updated guidance to EPs and eligible hospitals who wish to join in our efforts to explore the electronic exchange of information. Any testing should be based on the principal of electronic exchange of information from certified EHR technology either directly to the States or through an intermediary. For purposes of the programs in this proposed rule it would be counterproductive for an intermediary to collect information through paper abstraction.

We will issue further instructions on the specifics for submitting attestation through established outreach venues.

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

As described below, the HITECH Act requires the Secretary to post online the names of Medicare EPs and eligible hospitals and CAHs who are meaningful EHR users for the relevant payment year. Section 1903(t)(2) of the Act also requires us to ensure that EPs do not receive an EHR incentive payment under both Medicare and Medicaid. To fulfill these mandates, we must collect several data elements from EPs and eligible hospitals. Beyond these two direct HITECH Act requirements, CMS and the States also require certain data in order to accurately calculate and distribute the incentive payments.

a. Online Posting

Section 1848(o)(3)(D) of the Act requires the Secretary to list in an easily understandable format the names, business addresses, and business phone numbers of the Medicare EPs and, as

determined appropriate by the Secretary, of group practices receiving incentive payments for being meaningful EHR users under the Medicare FFS program on our internet Web site. We do not propose to post information on group practices because we do not propose to base incentive payments at the group practice level. Section 1886(n)(4)(B) of the Act, as added by section 4102(c) of the HITECH Act, requires the Secretary to list in an easily understandable format the names and other relevant data, as she determines appropriate, of eligible hospitals and CAHs who are meaningful EHR users under the Medicare FFS program, on our internet Web site. Eligible hospitals and CAHs will have the opportunity to review the list before the list is publicly posted. Sections 1853(m)(5) and 1853(l)(7) of the Act, as added by sections 4101(c) and 4102(c) of the HITECH Act, require the Secretary to post the same information for EPs and eligible hospitals in the MA program as would be required if they were in the Medicare FFS program. Additionally, the Secretary must post the names of the MA organizations receiving the incentive payment or payments. We propose to collect the information necessary to post the name, business address and business phone numbers of all EPs, eligible hospitals and CAHs participating in the Medicare FFS and MA EHR incentive programs, and to post this information on our Web site.

b. Program Election Between Medicare FFS/MA and Medicaid for EPs

Section 1903(t)(2) of the Act prohibits an EP from receiving incentive payments under the Medicaid program unless the EP has waived any rights to incentive payments under the Medicare FFS or MA programs. Furthermore, section 1903(t)(7) of the Act requires the Secretary to assure no duplication of funding with respect to the Medicaid program, and the physician and MA incentive payments under sections 1848(o) and 1853(l) of the Act. This waiver and non-duplication requirement applies only to EPs meeting both the Medicare FFS/MA and Medicaid EHR incentive programs eligibility criteria, and does not apply to hospitals (which are eligible to receive incentive payments from both Medicare and Medicaid simultaneously). Proposed § 495.10 would allow an EP meeting the eligibility criteria for both the Medicare FFS/MA and Medicaid programs to participate in either program. Further, the EP would be permitted to change his or her election once during the life of the EHR

incentive programs after making the initial election. We believe this one-time election rule would allow an EP whose patient volume no longer makes him or her eligible for the Medicaid program to nevertheless continue to receive incentive payments that would encourage the meaningful use of certified EHR technology. For example, an EP who moves to a different practice or geographically relocates practices may reduce his or her Medicaid patient volume, and therefore become ineligible for the Medicaid incentive payments. Allowing this EP to continue to receive incentive payments under Medicare (if eligible) would continue the incentive for meaningfully using EHR technology, and would allow EPs a certain amount of flexibility in their operations. While allowing this flexibility creates administrative complexity, we believe a significant number of EPs could have their participation in the EHR incentive programs endangered due to changing circumstances unrelated to the EHR incentive programs.

Under our proposal, if an EP does decide to switch programs, we propose that the EP would continue in the next program at whichever payment year he or she would have attained had the EP not chosen to switch. For example, if an EP decides to switch after receiving his or her Medicare FFS incentive payment for their second payment year, then the EP would be in its third payment year for purposes of the Medicaid incentive payments. Even after lining up the payment years, it is possible for an EP to exceed the payment cap under Medicaid by switching programs at the right time. We do not believe that the Congress intended for the payment caps to be exceeded under any circumstance, and therefore propose that no EP should receive more than the maximum incentive available to them under Medicaid, which is the higher of the two caps. The last year incentive payment would be reduced if awarding the EP the full amount would exceed the overall maximum available under Medicaid. This is possible if an EP receives their first two payment years from Medicare and then the last four from Medicaid, as the cap would be exceeded by \$250. An EP who switches from Medicaid to Medicare could exceed the Medicare threshold in a number of circumstances; however, since they cannot exceed the Medicaid threshold under any circumstance, we propose to pay the incentive for which they are eligible for a given payment year in whichever program they are in for that payment year. Finally, we propose that the last year for making an

incentive payment program switch would be CY 2014. In making this proposal, we considered that it is both the last year an EP can enroll in the Medicare EHR incentive program, and also the last year before the payment adjustments under Medicare can begin. We request comments on the necessity of the ability to switch and the allowed timing for such switches.

c. Data To Be Collected

In addition to information regarding the demonstration of meaningful use, in § 495.10 of this proposed rule we propose to collect the following administrative data for the Medicare and Medicaid EHR incentive programs to fulfill our requirements of online posting, avoidance of duplication of incentive payments, and to ensure accurate and timely incentive payments:

- Name, NPI, business address, and business phone of each EP or eligible hospital.
 - Taxpayer Identification Number (TIN) to which the EP or eligible hospital wants the incentive payment made. For Medicaid EPs this must be consistent with assignment rules at § 495.10.
 - For EPs, whether they elect to participate in the Medicare EHR incentive programs or the Medicaid EHR incentive program.
 - For eligible hospitals, their CCN.
- To coordinate with the States to avoid duplication of payments, we further propose to make available to the States through a single repository the following additional data:
- Whether an EP or eligible hospital is a meaningful EHR user, and
 - The remittance date and amount of any incentive payments made to an EP or eligible hospital.

CMS, our contractors, and the States will have access to these six data elements through a single repository maintained by CMS. The States will have to provide information to us on whether EPs or eligible hospitals are eligible for the Medicaid incentive program, whether EPs or eligible hospitals participating in the Medicaid program are meaningful EHR users, and when any Medicaid incentive payments are made and the amount of the payment. We will put in place processes for an EP or eligible hospital to change their information, including the one-time switch in EHR incentive program election by EPs.

6. Hospital-Based Eligible Professionals

Section 1848(o)(1)(C)(i) of the Act, as added by section 4101(a) of the HITECH Act, states that hospital-based EPs are not eligible for the Medicare incentive

payments. Similarly, the majority of hospital-based EPs will not be eligible for Medicaid incentive payments under 1903(t)(2)(A) of the Act (the only exception to this rule is for those practicing predominantly in an FQHC or RHC). Section 1848(o)(1)(C)(ii) of the Act defines the term “hospital-based eligible professional” to mean an EP, such as a pathologist, anesthesiologist, or emergency physician, who furnishes substantially all of his or her Medicare-covered professional services during the relevant EHR reporting period in a hospital setting (whether inpatient or outpatient) through the use of the facilities and equipment of the hospital, including the hospital’s qualified EHRs. This section indicates that the determination of whether an EP is a hospital-based EP shall be made on the basis of the site of service, as defined by the Secretary, and without regard to the type of service provided by the EP or any employment or billing arrangement between the EP and any other provider (for example, the hospital-based determination for an EP would not be affected by whether the EP is an employee of the hospital, under a contractual relationship with the hospital, or with respect to where he or she has made a reassignment to the hospital for Part B billing purposes). Section 1903(t)(3)(D) of the Act defines hospital-based EP in nearly identical terms.

In addition, as discussed below, section 1848(a)(7)(D) of the Act, as added by section 4101(b) of the HITECH Act, exempts hospital-based EPs from the downward payment adjustment applied under section 1848(a)(7)(A)(i) of the Act to covered professional services provided during a payment year by EPs who are not meaningful EHR users for the relevant payment year beginning in 2015.

If an EP is providing “substantially all” of their services in the hospital, we believe it is reasonable to assume that the EP is also using the facilities and equipment of the hospital, including any qualified EHR implemented by the hospital. The statute uses “facilities and equipment” to determine whether an EP is a hospital-based EP. As “facilities and equipment” would generally be understood to apply to the hospital building and its medical and other equipment that is used in furnishing medical services, we believe it is reasonable to assume that an EP providing substantially all of their services in a hospital is providing these services in the hospital building and generally is also using its equipment, including qualified EHRs, and not bringing his or her own equipment to

the hospital to provide medical services. Similarly, it seems reasonable to assume that the statute contemplates that an EP that uses the hospital’s facilities and equipment would also be using the hospital’s EHR system and should be ineligible for an incentive payment. We seek comment as to whether EPs are using qualified EHR of the hospital in ambulatory care settings.

As noted previously, the statute provides that hospital-based EPs, “such as a pathologist, anesthesiologist, or emergency physician,” are those EPs that provide substantially all of their Medicare-covered professional services in a “hospital setting (whether inpatient or outpatient).” Because the HITECH Act does not define the term “hospital setting,” we looked to existing statutes and regulations that define and describe hospital settings for guidance in defining “hospital setting” for purposes of this proposed rule. We welcome comments on alternative approaches to interpreting the meaning of “hospital setting.”

First, section 1861(e) of the Act defines the term a “hospital” to mean an institution that “is primarily engaged in providing, by or under the supervision of physicians, to inpatients (A) diagnostic services and therapeutic services for medical diagnosis, treatment, and care of injured, disabled, or sick persons, or (B) rehabilitation services for the rehabilitation of injured, disabled, or sick persons.” Therefore, we propose that EPs that practice primarily in inpatient hospital settings, as referenced in section 1861(e) of the Act, be considered hospital-based EPs.

Because the parenthetical after the term “hospital setting” in the statutory definition of hospital-based EP specifically refers to both inpatient and outpatient hospital settings, we believe the term “hospital setting” should be defined to also include the outpatient setting. So although a “hospital” is an institution that primarily provides inpatient services, we propose to define the term “hospital setting” for purposes of the Medicare and Medicaid EHR incentive payment programs to also include all outpatient settings where hospital care is furnished to registered hospital outpatients. For purposes of Medicare payment and conditions of participation, it is CMS’s longstanding policy to consider as outpatient hospital settings those outpatient settings that are owned by and integrated both operationally and financially into the entity, or main provider, that owns and operates the inpatient setting. For example, we consider as outpatient hospital settings all types of outpatient care settings in the main provider, on-

campus and off-campus provider-based departments (PBDs) of the hospital, and entities having provider-based status, as these entities are defined in § 413.65.

In accordance with our regulations at § 413.65, a provider-based department or entity must operate under the ownership and financial and administrative control of the main provider. We also note that the provider-based department or entity of the hospital comprises both the physical facility where services are furnished and the personnel and equipment used to care for patients in those settings. In addition, § 413.65(d) specifies that the financial operations of provider-based departments or entities must be fully integrated within the financial system of the main provider. Medicare makes payment to the hospital under the outpatient payment system for the facility resources required for care that is furnished to hospital outpatients in its provider-based departments and entities, regardless of the specific type of hospital outpatient setting. Moreover, Medicare pays EPs for their professional services furnished to hospital outpatients at the facility rate under the Medicare Physician Fee Schedule (MPFS), also regardless of the specific type of hospital outpatient setting, recognizing that in all hospital outpatient settings the hospital bears the cost of personnel, equipment, and supplies for which payment would otherwise be made to the EP under the MPFS for services furnished in a non-facility setting. Section 413.65(d) also requires that the medical records for patients treated in the provider-based department or entity must be integrated into a unified retrieval system (or cross reference) of the main provider. Moreover, an eligible hospital will receive an incentive payment for its medical records system if such system is considered certified EHR technology and is meaningfully used by the hospital consistent with the requirements of the final rule to this rule. Because, by definition of the requirements for provider-based departments and entities, EPs who furnish substantially all of their covered professional services to hospital outpatients use the hospital’s facility and equipment, including the integrated medical record system, for which payment is made by Medicare to the hospital, we believe these EPs should be considered hospital-based EPs, and thus excluded from the Medicare EP EHR incentive payments. This is fully consistent with the definition of hospital-based EPs in section 1848(o)(1)(C)(ii) of the Act.

In summary, we propose that EPs that provide substantially all of their professional services in the inpatient hospital setting, in any type of outpatient hospital setting, or in any combination of inpatient and outpatient hospital settings, be considered hospital-based EPs.

We propose to consider the use of place of service (POS) codes on physician claims to determine whether an EP furnishes substantially all of their professional services in a hospital setting and is, therefore, hospital-based. This code set is required for use in the implementation guide adopted as the national standard for electronic transmission of professional health care claims under the provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). HIPAA directed the Secretary of HHS to adopt national standards for electronic transactions. These standard transactions require all health plans and providers to use standard code sets to populate data elements in each transaction. The Transaction and Code Set Rule (65 FR 50312) adopted the ASC X12N-837 Health Care Claim: Professional, volumes 1 and 2, version 4010, as the standard for electronic submission of professional claims. This standard names the POS code set currently maintained by CMS as the code set to be used for describing sites of service in such claims and is available at http://www.cms.hhs.gov/PlaceofServiceCodes/Downloads/POS_09_10_07_Rev_2_508.pdf.

From this code set, we propose to consider the use of the following POS codes indicating that the EP provided the service in an inpatient or any type of outpatient hospital setting (including a PBD of a hospital) to determine whether an EP is a hospital-based eligible professional:

- 21—Inpatient Hospital—is a facility, other than psychiatric, which primarily provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services by, or under, the supervision of physicians, to patients admitted for a variety of medical conditions.
- 22—Outpatient Hospital—is a portion of a hospital which provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization.
- 23—Emergency Room, Hospital—is a portion of a hospital where emergency diagnosis and treatment of illness or injury is provided.

Place of service codes 22 (Outpatient Hospital) and 23 (Emergency Room,

Hospital) are commonly recognized to be outpatient departments of the hospital. An outpatient department of a hospital will either meet the definition of the “main provider,” a “department of a provider,” or of having “provider-based status” as those terms are used in § 413.65. Place of service codes 22 and 23 are used to describe hospital outpatient settings that meet these definitions under § 413.65 and are also subject to the conditions of participation under part 482.

The statutory definition of hospital-based EP provides that to be considered a hospital-based EP, the EP must provide “substantially all” of his or her covered professional services in a hospital setting, which we propose to encompass all hospital inpatient and outpatient settings, including all settings that meet the definition of the main provider, department of a provider, or of having provider-based status. Therefore, we must identify the minimum percentage of an EP’s covered professional services that must be provided in a hospital setting in order for the EP to be considered as providing “substantially all” of his or her covered professional services in a hospital setting. We would define “substantially all” as furnishing at least 90 percent of services in a hospital setting, either inpatient or outpatient. We believe this threshold appropriately balances our competing goals of ensuring that professionals are encouraged to participate in the incentive program and avoid duplicate payments to a professional who is primarily using the EHR technology of the hospital in which he or she furnishes services. While we considered using 75 percent as a threshold for determining whether an EP is an hospital-based EP, we are concerned that such a standard could exclude EPs from receiving incentive payments that perform a minority but significant percentage of their services outside of inpatient or outpatient hospital settings and would have offices separate and independent from the hospital where they provide patient care services and for which they would have costs to obtain an EHR system. Based on an analysis of 2008 Medicare claims data, if we define “substantially all” of covered services in a hospital setting to mean that 75 percent or more of an EP’s allowed services are associated with one of the place of service codes listed above, we estimate that 65 percent of EPs would be considered eligible to receive an EHR incentive payment. If we increase this criterion to 90 percent, we estimate that 68 percent of EPs would be eligible for the EHR incentive

payment. In other words, 3 percent fewer EPs would be ineligible for the EHR incentive payments if we define “substantially all” to mean at least 90 percent rather than at least 75 percent.

Because EPs providing 90 percent or more of their services in one of these sites as described above are not likely to expend significant resources related to EHRs in other, non-hospital settings, we believe this proposal is most consistent with the law’s intent of not providing incentive payments to EPs that are providing substantially all of their services in a hospital setting (whether inpatient or outpatient). However, we are open to comments on other proposals that are consistent with the law’s intent of not providing incentive payments to hospital-based physicians as defined in HITECH. In our proposed approach, a hospital-based eligible professional would be ineligible to receive an EHR incentive payment under either Medicare or Medicaid, regardless of the type of service provided, if more than 90 percent of their services are identified as being provided in places of service classified under place of service codes 21, 22, or 23.

Accordingly, for both Medicare and Medicaid incentive payment purposes, we propose that a hospital-based eligible professional is defined as an EP who furnishes 90 percent or more of their covered professional services in any of the above listed places of service. A hospital-based EP would be ineligible to receive EHR incentive payments. (Based on preliminary claims data from the first 9 months of 2009, CMS currently estimates that, under this proposed definition, about 27 percent of Medicare EPs (physicians) would be considered hospital-based and thus not eligible to receive any incentive payments. We do not have any data on Medicaid practitioners.) We propose to make this determination, for Medicare incentive payment purposes, as to whether or not an EP is hospital-based by annually analyzing an EP’s claims history from the prior year. Therefore, for example, based on such analysis, an otherwise EP would be considered a hospital-based EP and be ineligible for incentive payments in 2011 if he/she provided 90 percent or more of his/her allowed services in one of the above listed places of service based on their 2010 Medicare claims data. The hospital-based status of each EP would be reassessed each year, using claims data from the year immediately preceding the payment year. For Medicaid purposes, we are proposing that State Medicaid agencies make the determination about whether or not an

EP is hospital-based by analyzing an EP's Medicaid claims data, or in the case of EPs who deliver care via Medicaid managed care programs, by analyzing either encounter data or other equivalent data sources, at the State's option. There is an interest in assuring that nearly all primary care providers are meaningful users of EHR technology by 2014. However, this objective may not be reached because of several factors.

- Some primary care EPs who provide services to Medicare and Medicaid beneficiaries would be ineligible for the incentive payments. For example, we currently estimate that under this proposal, 12–13 percent of family practitioners under Medicare would be considered hospital-based under our proposed definition of hospital-based EP, and therefore would not be eligible for the EHR incentive payments. (Note that we believe that these data could be applied generally to Medicaid physicians as well. However, Medicaid EPs include other practitioners who also must meet hospital-based eligibility requirements, some of whom provide primary care services such as nurse practitioners.) Although many of these family practitioners may be serving in nonprimary care roles within the hospital setting (such as in emergency departments or functioning as hospitalists), those EPs performing primary care services in the hospital setting would also not be eligible to receive EP incentive payments. If these EPs were eligible to receive incentive payments, some might reassign them to the hospital, and the hospital could then use the EP's incentive payments for additional integrated outpatient EHR systems.

- As will be explained in the next section of this proposed rule, the hospital's total incentive payment is based on total inpatient services. As result, a hospital with a large outpatient department will not receive a higher incentive payment as a result of their outpatient services.

- Finally, as previously discussed, we are proposing that the Stage 1 meaningful use criteria for eligible hospitals apply only to a hospital's inpatient setting.

Because of these factors, we are concerned that hospital investment in their outpatient primary care sites is likely to lag behind their investment in their inpatient EHR systems. To address these concerns, as part of future rulemaking, we plan to consider ways to realign the meaningful use objectives and criteria to include a broader definition of hospital care to include

outpatient services. We believe this could provide an important incentive for hospital investment in EHRs for their outpatient primary care sites. We welcome comments on these issues including other ways that CMS, under the current statute, could help meet the objective that nearly all primary care providers are meaningful users of EHR technology by 2014.

We also seek comment on the extent to which hospitals install EHRs in their outpatient clinics as part of their adoption of EHRs. In addition, we seek comment on the way that hospitals with provider-based entities meet the provider-based requirements at 42 CFR 413.65(d) if they have EHRs in any or all parts of the hospital.

Finally, we seek comment on whether we should use another method for defining hospital-based EPs than what we have proposed here. Any comments should address implementation based on the specific POS codes identified, and/or any complexities that would result from not including all outpatient settings owned and operated by and integrated with the hospital in the determination of whether an EP is hospital-based.

7. Interaction With Other Programs

The HITECH Act addresses interactions between the Medicare EHR incentive program and the E-prescribing Incentive Program authorized by MIPPA. Under section 1848(m)(2)(D) of the Act, as added by section 4101(f)(2)(B) of the HITECH Act, if a Medicare FFS or MA EP receives an incentive payment from the Medicare EHR incentive program, the EP (or group practice) is not eligible to also receive the incentive payment under the E-prescribing Incentive Program created by MIPPA. Given the payment timelines proposed in this rule for the Medicare EHR incentive program and the existing payment timeline for the E-prescribing Incentive Program, we will know whether an EP received a Medicare EHR incentive payment before the E-Prescribing Incentive Program payment is calculated. Thus we will exclude those EPs (or group practices) who accept a Medicare EHR incentive payment for a given year from being eligible for the E-Prescribing Incentive Program payment for that same year. EPs receiving a Medicaid EHR incentive payment would remain eligible for the Medicare MIPAA E-Prescribing Incentive Program payment.

As the HITECH Act does not specify any other restrictions on participation in other programs and participation in the Medicare and Medicaid EHR incentive programs, we do not propose any other

restrictions. There may be opportunities to avoid duplication of reporting requirements among our various programs. In section II.A.3. of this proposed rule, we discuss how we will avoid duplication of reporting requirements for clinical quality measures.

B. Medicare Fee-for-Service Incentives

1. Incentive Payments for Eligible Professionals (EP)

Section 1848(o)(1)(A) of the Act, as amended by section 4101(a) of the HITECH Act, provides for incentive payments to EPs who are meaningful users of certified EHR technology during the relevant EHR reporting periods. Section 1848(o)(1)(A)(i) of the Act provides that EPs who are meaningful EHR users during the relevant EHR reporting period are entitled to an incentive payment amount, subject to an annual limit, equal to 75 percent of the Secretary's estimate of the Medicare allowed charges for covered professional services furnished by the EP during the relevant payment year. Under section 1848(o)(1)(B)(ii)(VI) of the Act, an EP is entitled to an incentive payment for up to 5 years. In addition, in accordance with section 1848(o)(1)(A)(ii) of the Act, there shall be no incentive payments made with respect to a year after 2016. The incentive payments would be disbursed from the Federal Supplementary Medical Insurance Trust Fund, as provided for under section 1848(o)(1)(A)(i) of the Act. As noted in section II.A. of this proposed rule, EPs who qualify for both the Medicare and Medicaid incentive payments must elect to receive payments from one program or the other.

a. Definitions

In accordance with section 1848(o)(5)(C) of the Act, we propose to add a definition of the term "eligible professional" in our regulations at § 495.100 to mean a physician as defined under section 1861(r) of the Act. Section 1861(r) of the Act defines the term "physician" to mean the following five types of professionals, each of which must be legally authorized to practice their profession under state law: A doctor of medicine or osteopathy, a doctor of dental surgery or dental medicine, a doctor of podiatric medicine, a doctor of optometry, or a chiropractor. As discussed in section II.B.1.a of this proposed rule, in accordance with section 1848(o)(1)(C) of the Act, hospital-based EPs are not eligible for an incentive payment.

Section 1848(o)(5)(A) of the Act defines covered professional services as having the same meaning as in section 1848(k)(3) of the Act, that is, services furnished by an eligible professional for which payment is made under, or is based on, the Medicare physician fee schedule.

In accordance with section 1848(a)(1) of the Act, the Medicare allowed charge for covered professional services is the lesser of the actual charge or the Medicare physician fee schedule amount established in section 1848 of the Act. As specified under section 1848(o)(1)(A)(i), the Secretary's estimate of allowed charges is based on claims submitted to Medicare no later than 2 months following the end of the relevant payment year. We propose to codify these specifications and definitions in our regulations at [cite proposed regulation range].

b. Incentive Payment Limits

Section 1848(o)(1)(B)(i) of the Act sets forth the annual limits on the EHR-

related incentive payments to EPs. Specifically, section 1848(o)(1)(B) of the Act provides that the incentive payment for an EP for a given payment year shall not exceed the following amounts:

- For the EP's first payment year, for such professional, \$15,000 (or, \$18,000 if the EP's first payment year is 2011 or 2012).
- For the EP's second payment year, \$12,000.
- For the EP's third payment year, \$8,000.
- For the EP's fourth payment year, \$4,000.
- For the EP's fifth payment year, \$2,000.
- For any succeeding year, \$0.

Under section 1848(o)(1)(B)(iv) of the Act, for EPs who predominantly furnish services in a geographic HPSA (as designated by the Secretary under section 332(a)(1)(A) of the Public Health Service (PHS) Act), the incentive payment limitation amounts for each payment year are increased by 10 percent. Section 1848(o)(1)(B)(iii) of the Act also provides for a phased reduction

in payment limits for EPs who first demonstrate meaningful use of certified EHR technology after 2013. Specifically, if the EP's first payment year is after 2013, then the annual limit on the incentive payment equals the annual limit applicable to an EP whose first payment year is 2013. Accordingly, if the EP's first payment year is 2014, the EP's maximum incentive payment will be \$12,000 in 2014, \$8,000 in 2015, and \$4,000 in 2016. Section 1848(o)(1)(B)(v) of the Act provides that if the EP's first payment year is after 2014, then the applicable incentive payment limit for such year and any subsequent year shall be \$0. In other words, an EP who does not qualify to receive an EHR-related incentive payment prior to 2015 will not receive any of these incentive payments. Table 22 shows the maximum incentive payment amounts available to EPs under Medicare FFS. (As noted above and discussed further below, these limits are increased by 10 percent for EPs who predominantly furnish services in an HPSA.)

TABLE 22—MAXIMUM TOTAL AMOUNT OF EHR INCENTIVE PAYMENTS FOR A MEDICARE EP WHO DOES NOT PREDOMINANTLY FURNISH SERVICES IN A HPSA

Calendar year	First CY in which the EP receives an incentive payment				
	2011	2012	2013	2014	2015—subsequent years
2011	\$18,000
2012	12,000	\$18,000
2013	8,000	12,000	\$15,000
2014	4,000	8,000	12,000	\$12,000
2015	2,000	4,000	8,000	8,000	\$0
2016	2,000	4,000	4,000	0
Total	44,000	44,000	39,000	24,000	0

The following examples illustrate how the payment amount would be determined:

• *Example 1:* EP that receives the maximum payment. For payment year 2011, the incentive payment for an EP would be, subject to a payment limit of \$18,000, equal to 75 percent of the EP's Medicare physician fee schedule allowed charges for CY 2011 (in this case, the maximum allowed charges recognized for the purposes of the incentive, or $\$24,000 \times .75 = \$18,000$), estimated based on claims for covered professional services furnished by the EP from January 1, 2011 through December 31, 2011, and submitted to the appropriate Medicare administrative contractor (MAC/carrier) on or before February 29, 2012.

• *Example 2:* EP that receives less than the maximum payment. Assume for this example that the EP's estimated total allowed charges for covered professional services are \$10,000 which is less than the \$24,000 maximum allowed charges that could be

recognized for purposes of this incentive. Therefore, for payment year 2011, the incentive payment in this case would be, $\$10,000 \times .75 = \$7,500$, based on claims for covered professional services furnished by the EP from January 1, 2011 through December 31, 2011, and submitted to the appropriate Medicare administrative contractor (MAC) or carrier on or before February 29, 2012.

We propose, for each subsequent payment year, to use the annual allowed charges and claims in a similar manner to calculate the Secretary's estimate of allowed charges for purposes of computing the incentive payment.

• *Example:* For payment year 2012, the incentive payment issued to an EP would be, subject to a payment limit (that is, \$18,000 if it is the first payment year, \$12,000 if it is the second payment year), equal to 75 percent of the EP's Medicare physician fee schedule allowed charges for CY 2012, based on claims for covered professional services

performed by the EP from January 1, 2012 through December 31, 2012, and submitted to the appropriate Medicare administrative contractor (MAC/carrier) on or before February 28, 2013.

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

Section 1848(o)(1)(B)(iv) of the Act provides that the amount of the annual incentive payment limit for each payment year be increased by 10 percent for EPs who predominantly furnish services in an area that is designated by the Secretary (under section 332(a)(1)(A) of the PHS Act) as a geographic health professional shortage area (HPSA). Section 332(a)(1)(A) of the PHS Act refers to geographic HPSAs, or areas that have been determined to have a shortage of

health professionals, based on the population-to-provider ratio and other factors. HPSAs are located in every State, and in both rural and urban areas.

Geographic HPSAs are defined in 42 CFR Part 5 and include primary medical care, dental, and mental health HPSAs. In accordance with the statute, we will increase the limits per payment year by 10 percent for EHR-related incentive payments to EPs who predominantly furnish covered professional services in a geographic primary medical care, dental, or mental health HPSA.

We propose that an EP be considered as “predominantly” furnishing covered professional services in a geographic HPSA if more than 50 percent of the EP’s Medicare covered professional services are furnished in a geographic HPSA. Using “more than 50 percent” as the criterion to define “predominantly” is consistent with how the term is defined in general parlance as well as how the definition is used for purposes of other aspects of the Medicare program.

To determine whether an EP has furnished more than 50 percent of his/her covered professional services in a geographic HPSA, we propose to utilize frequency of services provided over a 1-year period from January 1 to December 31, rather than basing it on the percentage of allowed charges. Our data indicates that most physicians either provide all or none of their services in a geographic HPSA, so we believe that our proposal to base eligibility for the 10 percent EHR HPSA payment limit increase on frequency, rather than allowed charges, will have little or no impact on the determination of whether an EP is eligible for the EHR HPSA payment limit increase. To apply the payment limit increase, we will first need to determine whether more than 50 percent of an EP’s covered professional services were furnished in a geographic HPSA during a particular payment year. We propose to first make the generally applicable incentive payment to the EP based on an EP’s estimated allowed charges for the relevant payment year.

Once we compile a full year of data, we would determine eligibility for the EHR HPSA payment limit increase for the payment year based on whether the EP provided more than 50 percent of his/her services in a geographic HPSA during the payment year. The determination would be made based on claims submitted not later than 2 months after the end of the year. If we determine that the EP provided more than 50 percent of his/her services in a geographic HPSA and is therefore eligible for the EHR HPSA payment

limit increase, we would then make an additional lump sum payment to reflect that increased limit amount based on the estimated allowable charges for that EP for the prior year. We propose that the additional amount would be paid no later than 120 days after the end of the prior year for which the EP was eligible for the 10 percent EHR HPSA payment limit increase.

Most physicians furnishing services in a HPSA furnish 100 percent of their covered services in a HPSA. Based on our data, we found very few physicians provide even a modest percentage of their services across HPSA and non-HPSA areas. We estimate that about 17 percent of EPs would qualify for the 10 percent EHR HPSA payment limit increase, provided they satisfy the other requirements for the incentive payment. Section 1848(o)(1)(B)(iv) of the Act also authorizes us to apply the provisions of sections 1833(m) and (u) of the Act in implementing this 10 percent EHR HPSA payment limit increase, as the Secretary determines appropriate. Section 1833(m) of the Act establishes the HPSA bonus program, which provides a 10 percent bonus to physicians who furnish Medicare covered professional services in a geographic HPSA. Section 1833(u) of the Act establishes the Physician Scarcity Area bonus program, which provided a 5 percent bonus to physicians who furnish Medicare covered professional services in areas that are determined to physician scarcity areas. (Note: The authority for the Physician Scarcity Area program ended on June 31, 2008.)

Section 1833(m)(1) of the Act provides that physicians who furnish covered professional services in a year in an area that is designated as a geographic HPSA prior to the beginning of the year are eligible to receive the HPSA bonus for services furnished during the current year. We have interpreted this to mean that bonus payments should continue throughout the current year, even if the area loses its designation as a geographic HPSA during the current year. Physicians furnishing covered professional services in an area that is not designated as a geographic HPSA by December 31 of the prior year are not eligible to receive the HPSA bonus for the current year, even if the area is subsequently designated as a geographic HPSA during the current year. We propose to apply these same rules for the 10 percent EHR HPSA payment limit increase provided under section 1848(o)(1)(B)(iv) of the Act. Specifically, we propose that EPs who predominately furnish covered professional services in an area that is

designated as a geographic HPSA as of December 31 of the prior year would be eligible to receive the 10 percent EHR HPSA payment limit increase during the current year, provided the EP qualifies for the EHR HPSA payment limit for the current year. For example, an EP furnishing a covered professional service in an area that was designated as a geographic HPSA as of December 31, 2010, and who qualifies to receive the EHR HPSA payment in 2011, also would receive a 10 percent EHR incentive payment limit increase for 2011.

Section 1833(m)(2) of the Act also provides that geographic HPSAs that consist of an entire county be identified and the bonus paid automatically. We publish a list annually of the zip codes that are in these areas on our Web site at http://www.cms.hhs.gov/HPSAPhysicianBonuses/01_Overview.asp#TopOfPage. Physicians furnishing Medicare covered professional services in a zip code that is on this list automatically receive the HPSA bonus payment. Physicians furnishing Medicare covered professional services in a zip code that is not on this list but that was designated as a geographic HPSA as of December 31 of the prior year must use a modifier when submitting a Medicare claim in order to receive the HPSA bonus.

We note that we would only list a zip code on our Web site if the entire geographic area encompassed by the zip code is designated as a geographic HPSA. If a zip code encompasses both areas designated as a geographic HPSA and areas that are not a geographic HPSA, we will not list the zip code on our Web site. Our list also will not include zip codes for areas designated as geographic HPSAs after we create the zip code list (but before December 31). EPs furnishing Medicare covered professional services in an area eligible for the EHR HPSA payment limit increase that is not included in the list of zip codes for automatic payment would need to use a modifier when submitting a claim to identify their eligibility for the HPSA EHR payment limit increase.

Table 23 shows the maximum total EHR HPSA payment limit for an EP who predominantly furnishes covered professional services in a HPSA as described previously above for CYs 2011 through 2016. Table 24 shows the maximum additional amount of incentive payments for a Medicare EP who predominantly furnishes services in a HPSA. (That is, Table 24 shows the difference between Tables 22 and 23.)

TABLE 23—MAXIMUM TOTAL AMOUNT OF INCENTIVE PAYMENTS FOR A MEDICARE EP WHO PREDOMINANTLY PERFORMS SERVICES IN A HPSA

Calendar year	Year that EP becomes EHR user in a HPSA				2015 and subsequent years
	2011	2012	2013	2014	
2011	\$19,800
2012	13,200	\$19,800
2013	8,800	13,200	\$16,500
2014	4,400	8,800	13,200	\$13,200
2015	2,200	4,400	8,800	8,800	\$0
2016	2,200	4,400	4,400	0
Total	48,400	48,400	42,900	26,400	0

TABLE 24—MAXIMUM ADDITIONAL AMOUNT OF INCENTIVE PAYMENTS FOR A MEDICARE EP WHO PREDOMINANTLY PERFORMS SERVICES IN A HPSA

Calendar year	Year that an EP first receives the incentive payment for Medicare covered professional services furnished in a geographic HPSA				2015 and subsequent years
	2011	2012	2013	2014	
2011	\$1,800
2012	1,200	\$1,800
2013	800	1,200	\$1,500
2014	400	800	1,200	\$1,200
2015	200	400	800	800	\$0
2016	200	400	400	0
Total	4,400	4,400	3,900	2,400	0

d. Form and Timing of Payment

Section 1848(o)(1)(D)(i) of the Act, as amended by section 4101(a) of the HITECH Act, provides that the incentive payments may be disbursed as a single consolidated payment or in periodic installments as the Secretary may specify. We propose to make a single, consolidated, annual incentive payment to EPs. We believe that making a single, consolidated payment would be the least administratively burdensome for both CMS and most EPs. We expect that many EPs who demonstrate meaningful use of certified EHR technology will receive the maximum incentive payments. We propose that payments would be made on a rolling basis, as soon as we ascertain that an EP has demonstrated meaningful use for the applicable reporting period (that is, 90 days for the first year or a calendar year for subsequent years), and reached the threshold for maximum payment.

Section 1848(o)(1)(A) of the Act provides that “with respect to covered professional services provided by an eligible professional,” the incentive payment “shall be paid to the eligible professional (or to an employer or facility in the cases described in clause (A) of section 1842(b)(6)).” Section 1842(b)(6)(A) of the Act allows for reassignment to an employer or entity with which the physician has a valid contractual arrangement allowing the

entity to bill for the physician’s services. Therefore, EPs are allowed to reassign their incentive payment to their employer or an entity which they have a valid employment agreement or contract providing for such reassignment, consistent with all rules governing reassignments. The statute does not address the case where the EP has multiple employers/contractual arrangements, and it would be difficult operationally for CMS to allocate the incentive payment among two or more individuals/entities. Therefore, in § 495.10(e) we are proposing to preclude an EP from reassigning the incentive payment to more than one employer or entity. We believe that the question of whether the EP has reassigned the incentive payment to the employer/entity under his or her contract with the employer/entity, including any pre-existing contract between the parties, is a matter of contract interpretation that should be resolved by the parties themselves. We note that nothing in the statute or our existing regulations would prohibit an EP from assigning to the employer/entity only the allowable charges for his or her professional services, with the EP retaining any incentive payment, or vice versa. If an EP will reassign his or her incentive payment to an employer/entity with which the EP has a contractual arrangement, the parties will need to

review their existing contract to determine whether it currently provides for reassignment of the incentive payment to the employer/entity or needs to be revised.

The statute provides that the incentive payment shall be paid to the employer or facility in the cases described in clause (A) of section 1842(b)(6) of the Act. This clause provides that payment for a service provided to an individual may not be paid to anyone other than the individual or the practitioner who provided the service, except that the practitioner may reassign his or her right to payment to his or her employer or an entity with whom he or she has a contractual arrangement if certain conditions are met. Any such authorization must be in accordance with our regulations at 42 CFR 424.73 and 42 CFR 424.80.

Section 1848(o)(1)(D)(ii) of the Act requires the Secretary to establish rules to coordinate the incentive payments made among practices for an EP furnishing covered professional services in more than one practice, including the application of the limits on the amounts of the incentive payments. To implement this requirement, we propose to use the EP’s Medicare enrollment information to determine whether an EP belongs to more than one practice (that is, whether the EP’s National Provider Identifier (NPI) is

associated with more than one practice). In cases where the EP is associated with more than one practice, we propose that EPs select one tax identification number to receive any applicable EHR incentive payment.

Although it would not be impossible for Medicare contractors to make proportional EHR incentive payments to each TIN associated with a provider, we believe this option would entail the creation of highly complex and potentially unwieldy administrative systems. Therefore, we believe our proposal to permit the EP to select one TIN to which we will make any EHR incentive payment is the most efficient alternative. We have proposed that payments would be made on a rolling basis, as soon as we ascertain that an EP has demonstrated meaningful use for the applicable reporting period (that is, 90 days for the first year or a calendar year for subsequent years), and reached the threshold for maximum payment. If we were to adopt an alternative policy, permitting EHR incentive payments to be made to multiple TINs, we would need to calculate the percentage of covered professional services billed by each TIN for that EP, and the total of any incentive payment amount would be divided and paid accordingly. Thus, a policy permitting payment to multiple TINs would conflict with our proposal to make payment on a rolling basis as EPs meet the criteria to receive the maximum EHR incentive payment. An additional confounding factor is the possibility that an EP might change group affiliations during the year. Therefore, we believe the most judicious policy would be to permit the EP to designate one TIN to which payment will be made.

e. 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. In general, beginning in 2015, if an EP is not a meaningful EHR user for any EHR reporting period for the year, then the Medicare physician fee schedule amount for covered professional services furnished by the EP during the year (including the fee schedule amount for purposes of determining a payment based on the fee schedule amount) is adjusted to equal the ‘applicable percent’ of the fee schedule amount (defined below) that would otherwise

apply. The HITECH Act includes a significant hardship exception, discussed below, which, if applicable, could exempt certain EPs from this payment adjustment. The payment adjustments will not apply to hospital-based EPs, as defined elsewhere.

The term ‘applicable percent’ means: “(I) for 2015, 99 percent (or, in the case of an EP who was subject to the application of the payment adjustment if the EP is not a successful electronic prescriber under section 1848(a)(5) for 2014, 98 percent);” “(II) for 2016, 98 percent; and (III) for 2017 and each subsequent year, 97 percent.”

In addition, section 1848(a)(7)(iii) of the Act provides that if for 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 from the applicable percent in the preceding year, but in no case shall the applicable percent be less than 95 percent. Significant Hardship Exception—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 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 exemption is subject to annual renewal, but in no case may an EP be granted a hardship exemption for more than 5 years.

We will include specific proposals to implement these payment adjustments for EPs who are not meaningful EHR users in future rulemaking prior to the 2015 effective date. We welcome comments on these payment adjustments and any comments received will be considered in developing future proposals to implement these provisions, including comments on the possible circumstances for which we should allow an EP to qualify for the significant hardship exception.

2. Incentive Payments for Hospitals
a. Definition of Eligible Hospital for Medicare

Section 1886(n) of the Act, as amended by section 4102(a)(1) of the HITECH Act, provides for incentive payments, beginning in FY 2011 (that is, October 1, 2010 through September 30, 2011) for eligible hospitals that are meaningful users of certified EHR technology during the EHR reporting period for the payment year. We are

proposing a new § 495.104 to implement this provision. For purposes of this provision, section 1886(n)(6)(B) of the Act defines “eligible hospitals” as “subsection (d) hospitals,” as that term is defined in section 1886(d)(1)(B) of the Act. Section 1886(d)(1)(B) of the Act generally defines a “subsection (d) hospital” as a “hospital located in one of the fifty States or the District of Columbia.” The term therefore does not include hospitals located in the territories or hospitals located in Puerto Rico. Section 1886(d)(9)(A) of the Act separately defines a “subsection (d) Puerto Rico hospital” as a hospital that is located in Puerto Rico and that “would be a subsection (d) hospital * * * if it were located in one of the 50 states.” Therefore, because section 4102(a)(1) of the HITECH Act does not refer to “subsection (d) Puerto Rico hospitals,” incentive payments for meaningful users of certified EHR technology are not available under this provision to hospitals located in Puerto Rico. The provision does apply to inpatient, acute care hospitals located in the State of Maryland. These hospitals are not currently paid under the IPPS in accordance with a special waiver provided by section 1814(b)(3) of the Act. Despite this waiver, the Maryland hospitals continue to meet the definition of a “subsection (d) hospital” because they are located in the 50 states. The statutory definition of a subsection (d) hospital also does not apply to hospitals and hospital units excluded under section 1886(d)(1)(B) from the IPPS, such as psychiatric, rehabilitation, long term care, children’s, and cancer hospitals. For purposes of this provision, we will provide incentive payments to hospitals as they are distinguished by provider number in hospital cost reports. Incentive payments for eligible hospitals will be calculated based on the provider number used for cost reporting purposes, which is the CCN of the main provider (also referred to as OSCAR number). Payments to eligible hospitals are made to each provider of record. The criteria for being a meaningful EHR user, and the manner for demonstrating meaningful use, are discussed in section B.2. of this proposed rule.

b. Incentive Payment Calculation for Eligible Hospitals

Section 1886(n)(2) of the Act, as amended by 4102(a) of HITECH, describes the methodology for determining the incentive payment amount for eligible hospitals that are meaningful users of certified EHR technology during the EHR reporting period for a payment year. In general,

that section requires the incentive payment for each payment year to be calculated as the product of: (1) An initial amount; (2) the Medicare share; and (3) a transition factor applicable to that payment year.

As amended by section 4201(a) of the HITECH Act, section 1886(n)(2)(A)(i) of the Act defines the initial amount as the sum of a “base amount,” as defined in section 1886(n)(2)(B) of the Act, and a “discharge related amount,” as defined in section 1886(n)(2)(C) of the Act. The base amount is \$2,000,000, as defined in section 1886(n)(2)(B) of the Act. The term “discharge related amount” is defined in section 1886(n)(2)(C) of the Act as “the sum of the amount, estimated based upon total discharges for the eligible hospital (regardless of any source of payment) for the period, for each discharge up to the 23,000th discharge as follows:

- (i) For the first through the 1,149th discharge, \$0.
- (ii) For the 1,150th through the 23,000th discharge, \$200.
- (iii) For any discharge greater than the 23,000th, \$0.

In addition to the base amount, the discharge related amount provides an additional \$200 for each hospital discharge during a payment year, beginning with a hospital’s 1,150th discharge of the payment year, and ending with a hospital’s 23,000th discharge of the payment year. No additional payment is made for discharges prior to the 1,150th discharge, or for those discharges subsequent to the 23,000th discharge.

Section 1886(n)(2)(C) of the Act, as amended by section 4102(a) of the HITECH Act, specifies that a “12-month period selected by the Secretary” may be employed for purposes of determining the discharge related amount. While the statute specifies that the payment year is determined based on a Federal fiscal year (FY), section 1886(n)(2)(C) of the Act provides the Secretary with authority to determine the discharge related amount on the basis of discharge data from a relevant hospital cost reporting period, for use in determining the incentive payment during a FY. FYs begin on October 1 of each calendar year, and end on September 30 of the subsequent calendar year. Hospital cost reporting periods can begin with any month of a calendar year, and end on the last day of the 12th subsequent month. For purposes of administrative simplicity and timeliness, we propose, for each eligible hospital during each incentive payment year, to use data on the hospital discharges from the hospital fiscal year that ends during the

FY prior to the FY that serves as the payment year as the basis for making preliminary incentive payments. Final payments would be determined at the time of settling the cost report for the hospital fiscal year that ends during the payment year, and settled on the basis of the hospital discharge data from that cost reporting period.

Example: FY 2011 begins on October 1, 2010 and ends on September 30, 2011. For an eligible hospital with a cost reporting period running from July 1, 2010 through June 30, 2011, we would employ the relevant data from the hospital’s cost reporting period ending June 30, 2010 in order to determine the incentive payment for the hospital during FY 2011. This timeline would allow us to have the relevant data available for determining payments in a timely manner for the first and subsequent payment years. This timeline would also render it unnecessary to develop a cumbersome process to extract and employ discharge data across more than one hospital cost reporting period in order to determine the discharge related amount for a FY-based payment period. However, final payments would be based on hospital discharge data from the cost report ending June 30, 2011, and determined at the time of settlement for that cost reporting period.

c. Medicare Share

As previously discussed, the initial amount must be multiplied by the Medicare share and an applicable transition factor to determine the incentive payment to an eligible hospital for an incentive payment year. As added by section 4102(a) of the HITECH Act, section 1886(n)(2)(D) of the Act defines the Medicare share for purposes of calculating incentive payments as a fraction based on estimated Medicare FFS and managed care inpatient bed days, divided by estimated total inpatient bed-days, modified by charges for charity care. This section specifies that the Medicare share fraction is determined for the incentive payment year “for an eligible hospital for a period selected by the Secretary.” As in the case of the discharge data discussed above, this clause provides the Secretary with authority to determine the Medicare share fraction on the basis of data from a relevant hospital cost reporting period, for use in determining the incentive payment during a FY. For purposes of administrative simplicity and timeliness equivalent to those discussed above with regard to discharge data, we propose, for each eligible hospital during each incentive payment year, to employ data on the hospital’s Medicare fee-for-service and managed care inpatient bed days, total inpatient bed-days, and charges for charity care from the hospital fiscal year that ends during the FY prior to the FY that serves as the

payment year as the basis for preliminary payment. Final payment would be made on the basis of the data from the hospital fiscal year that ends during the FY that serves as the payment year at the time of the settlement of the cost report for the latter period.

Section 1886(n)(2)(D) of the Act, as amended by section 4102 of the HITECH Act, defines the numerator and denominator of this fraction in terms of estimated Medicare FFS and managed care inpatient bed days, estimated total inpatient bed-days, and charges for charity care. Specifically, section 1886(n)(2)(D)(i) of the Act defines the numerator of the Medicare share fraction as the sum of—

- The estimated number of inpatient-bed-days (as established by the Secretary) which are attributable to individuals with respect to whom payment may be made under part A; and
- The estimated number of inpatient-bed-days (as so established) that are attributable to individuals who are enrolled with a MA organization under Part C.

We propose to determine the numbers of Medicare Part A and Part C inpatient-bed-days using the same data sources and methods for counting those days that we employ in determining Medicare’s share for purposes of making payments for direct graduate medical education costs, as provided under section 1886(h) of the Act and § 413.75 of our regulations. Specifically, we propose to derive “the estimated number of inpatient-bed-days * * * attributable to individuals with respect to whom payment may be made under part A” from lines 1, 6 through 9, 10 and 14 in column 4 on Worksheet S–3, Part I of the Medicare cost report. The data entered on these lines in the cost report include all patient days attributable to Medicare inpatients, excluding those in units not paid under the IPPS and excluding nursery days. Similarly, we propose to derive the “estimated number of inpatient-bed-days attributable * * * to individuals who are enrolled with a MA organization under Part C” from line 2 in column 4 on Worksheet S–3, Part I of the Medicare cost report. The methodology and data sources for making these bed day determinations are not only well established, but also well known and understood within the hospital community. We therefore see no reason to develop or propose any alternative approach for determining the “subsection (d) hospital” numbers of Medicare Part A and Part C inpatient-bed-days for purposes of calculating these incentive payments.

Section 1886(n)(2)(D)(ii) of the Act defines the denominator of the Medicare share fraction as the product of—

- The estimated total number of inpatient-bed-days with respect to the eligible hospital during such period; and
- The estimated total amount of the eligible hospital's charges during such period, not including any charges that are attributable to charity care (as such term is used for purposes of hospital cost reporting under Title XVIII), divided by the estimated total amount of the hospital's charges during such period.

As in the case of Medicare Part A and Part C inpatient-bed days, for purposes of determining total inpatient-bed days in the denominator of the Medicare share fraction, we propose to use the same data sources, and the same methods, that we employ in determining Medicare's share for purposes of making payments for direct graduate medical education costs. Specifically, we will derive the relevant data from lines 1, 6 through 9, 10 and 14 in column 6 on Worksheet S-3, Part I of the Medicare cost report. The data entered on these lines in the cost report include all patient days attributable to inpatients, excluding those in units not paid under the IPPS.

d. Charity Care

In determining the denominator of the Medicare share fraction, we also must determine any charges that are attributable to charity care furnished by an eligible hospital or CAH. The exclusion of charges attributable to charity care has the effect of decreasing the denominator of the Medicare share fraction as the proportion of charity care (charity care charge ratio) provided by a hospital increases. This is because the ratio of estimated total hospital charges, not including charges attributable to charity care, to estimated total hospital charges during a period decreases, relatively speaking, as a hospital provides a greater proportion of charity care. The effect of this factor on the denominator of the Medicare share fraction is therefore to decrease the denominator (as the total number of inpatient-bed days is multiplied by a relatively lower charity care charge ratio), as a hospital provides a greater proportion of charity care. A smaller denominator increases the Medicare share factor, providing for higher incentive payments, to a hospital that provides a greater proportion of charity care. Conversely, as a hospital provides a lower proportion of charity care, the ratio of estimated total hospital charges, not including charges attributable to

charity care, to estimated total hospital charges during a period increases. In this case, the effect of this factor on the denominator of the Medicare share fraction is therefore to increase the denominator (as the total number of inpatient-bed days is multiplied by a relatively higher charity care charge ratio), as a hospital provides a smaller proportion of charity care. A larger denominator in turn decreases the Medicare share factor, providing for lower incentive payments, as a hospital provides a lower proportion of charity care.

The data and methods for determining this charity factor for purposes of the Medicare share fraction warrants more extensive discussion. Section 112 of the Medicare, Medicaid, and State Children's Health Insurance Program (SCHIP) Balanced Budget Refinement Act of 1999 (Pub. L. 106-113) directs the Secretary to require prospective payment system hospitals to submit data on the costs incurred by the hospitals for providing inpatient and outpatient hospital services for which the hospitals are not compensated, including non-Medicare bad debt, charity care, and charges for medical and indigent care as part of the Medicare cost report.

In the August 1, 2000 **Federal Register** (65 FR 47054), we published a final rule that set forth changes to the IPPS and FY 2001 rates. In that final rule we responded to comments on implementing section 112 of Public Law 106-113. We informed the public that the hospital Medicare cost report and instructions would be revised to collect uncompensated care data. As a result of meeting with, and receiving input from, various hospital industry groups, "Worksheet S-10; Hospital Uncompensated and Indigent Care Data", was added to the Medicare cost reporting forms to implement section 112 of Public Law 106-113. The Worksheet S-10 was placed in effect for cost reporting periods beginning on or after April 30, 2002.

In May 2005, the Medicare Payment Advisory Commission (MedPAC) convened an expert panel to address concerns on the usefulness of the Worksheet S-10 data. Based on the panel discussion, MedPAC issued a list of recommended changes to the Worksheet S-10. In addition, in its March 2007 report to Congress, MedPAC recommended that the Secretary should improve the form and accompanying instructions for collecting data on uncompensated care in the Medicare cost report; and require hospitals to report using the revised

form as soon as possible. (Recommendation 2A-3)

In the August 22, 2007 **Federal Register** (72 FR 47406), we published a final rule responding to the MedPAC recommendation. We stated in that final rule that we were undertaking a major update to the Worksheet S-10 form and accompanying instructions based on the panel's discussions with MedPAC.

In the July 2, 2009 **Federal Register** (74 FR 31738), we accordingly published a proposed collection to revise the Hospital and Hospital Health Care Complex Cost Report, Form CMS-2552-10, which included a revised Worksheet S-10 form. This worksheet may change based on public comments. The revised cost report and accompanying instructions that include the definition of charity care based on MedPAC's recommendations are currently in the Paperwork Reduction Act clearance process. We anticipate that the revised hospital cost report will be effective for cost reporting periods beginning on or after February 1, 2010.

For the purposes of this proposed rule, we propose to define charity care as part of uncompensated and indigent care described for Medicare cost reporting purposes in the Medicare cost report instructions at section 4012 of the Provider Reimbursement Manual (PRM), Part 2; Worksheet S-10; Hospital Uncompensated and Indigent Care Data. Subsection (d) hospitals and CAHs are required to complete the Worksheet S-10.

As part of the Form CMS-2552-10 described above, the revised Worksheet S-10 instructions define uncompensated care as follows: "* * * charity care and bad debt which includes non-Medicare bad debt and non-reimbursable Medicare bad debt. Uncompensated care does not include courtesy allowances or discounts given to patients." These instructions further define charity care to include health services for which a hospital demonstrates that the patient is unable to pay. Charity care results from a hospital's policy to provide all or a portion of services free of charge to patients who meet certain financial criteria. For Medicare purposes, charity care is not reimbursable, and unpaid amounts associated with charity care are not considered as an allowable Medicare bad debt. Therefore, we are proposing to use the charity care charges that are reported on line 19 of the revised Worksheet S-10 in the computation of the Medicare share of the incentive payments. The revised instructions for line 19 of Worksheet S-10 state the following:

Enter the total initial payment obligation of patients who are given a full or partial discount, based on the hospital's charity care criteria (measured at full charges), for care delivered during this cost reporting period for the entire facility. For uninsured patients, including patients with coverage from an entity that does not have a contractual relationship with the provider (column 1), this is the patient's total charges. For patients covered by a public program or private insurer with which the provider has a contractual relationship (column 2), this is the deductible and coinsurance payments required by the payer. Include charity care for all services except physician and other professional services. Do not include charges for either uninsured patients given discounts without meeting the hospital's charity care criteria or patients given courtesy discounts. Charges for non-covered services provided to patients eligible for Medicaid or other indigent care program (including charges for days exceeding a length of stay limit) can be included, if such inclusion is specified in the hospital's charity care policy and the patient meets the hospital's charity care criteria.

Under section 1886(n)(2)(D) of the Act, if the Secretary determines that data are not available on charity care necessary to calculate the portion of the formula specified in clause (ii)(II) of section 1886(n)(2)(D) of the Act, the Secretary shall use data on uncompensated care and may adjust such data so as to be an appropriate proxy for charity care including a downward adjustment to eliminate bad debt data from uncompensated care data. In the absence of the data necessary for the Secretary to compute the amount described in clause (ii)(II) of section 1886(n)(2)(D) of the Act, the amount under such clause shall be deemed to be 1.

We believe that the charity care charges reported on line 19 of the Worksheet S-10 represent the most accurate measure of charity care charges as part of the hospital's overall reporting of uncompensated and indigent care for Medicare purposes. Therefore, since eligible hospitals and CAHs are required to complete the Worksheet S-10, if a hospital has not properly reported any charity care charges on line 19, we may question the accuracy of the charges used for computing the Medicare share of the incentive payments. With appropriate resources, we believe the charity care data can be obtained by the MAC. This data would be used to determine if the hospital's charity care criteria are appropriate, if a hospital should have reported charity care charges, and if the reported charges are proper. If we determine, as based on the determination of the MAC, that the hospital did not properly report charity care charges on the Worksheet S-10, then we propose to deem the

denominator in section 1886(n)(2)(D)(ii)(II) of the Act to be 1.

In this proposed rule, we are specifically soliciting public comments on the charity care financial criteria established by each hospital and reviewed by the MACs, the collection of charity care data on the Worksheet S-10, and whether proxies for charity care may be developed with other data available to us.

e. Transition Factor

As we have previously discussed, the initial amount must be multiplied not only by the Medicare share fraction, but also by an applicable transition factor in order to determine the incentive payment to an eligible hospital for an incentive payment year. Section 1886(n)(2)(E)(i) of the Act designates that the applicable transition factor equals 1 for the first payment year, three-fourths for the second payment year, one-half for the third payment year, one-fourth for the fourth payment year, and zero thereafter. However, section 1886(n)(2)(E)(ii) of the Act provides that if "the first payment year for an eligible hospital is after 2013, then the transition factor specified in this subparagraph for a payment year for such hospital is the same as the amount specified in clause (i) for such payment year for an eligible hospital for which the first payment year is 2013." Accordingly, if a hospital's first payment year is FY 2014, the applicable transition factor equals three-fourths for the first payment year (FY 2014), one-half for the second payment year (FY 2015), one-fourth for the third payment year (FY 2016), and zero thereafter. As discussed in more detail below, under section 1886(n)(2)(E)(ii) of the Act, the transition factor for a hospital for which the first payment year is after 2015 equals zero for all years. In other words, 2015 is the last year for which eligible hospitals may begin participation in the Medicare EHR Incentive Program.

Figure 1—Incentive Payment Calculation for Subsection D Hospitals

Incentive Amount = [Initial Amount] × [Medicare Share] × [Transition Factor]
 Initial Amount = \$2,000,000 + [\$200 per discharge for the 1,150th – 23,000th discharge]
 Medicare Share = Medicare / (Total * Charity Care) = [M / (T * C)]

M = [# of Inpatient Bed Days for Part A Beneficiaries] + [# of Inpatient Bed Days for MA Beneficiaries]
 T = [# of Total Inpatient Bed Days]
 C = [Total Charges – Charges for Charity Care] / [Total Charges]

*If data on charity care is not available, then the Secretary would use data on uncompensated care as a proxy. If the proxy data is not also available, then "C" would be equal to 1.

TRANSITION FACTOR

Consecutive payment year	Transition factor
1	1
2	3/4
3	1/2
4	1/4

f. Duration and Timing of Incentive Payments

Section 1886(n)(2)(E)(i) of the Act establishes that an eligible hospital that is a meaningful user of certified EHR technology could receive up to 4 years of financial incentive payments. The transition factor phases down the incentive payments over the 4-year period. Therefore, an eligible hospital that is a meaningful user of certified EHR technology during the relevant EHR reporting period, in payment year FY 2011, could receive incentive payments beginning with FY 2011 (transition factor equals 1), and for FY 2012 (transition factor equals three-fourths), 2013 (transition factor equals one-half), and 2014 (transition factor equals one-fourth) if they continue to be a meaningful user of certified EHR technology during the relevant EHR reporting periods.

Section 1886(n)(2)(E)(ii) of the Act establishes the range of time during which a hospital may begin to receive incentive payments, and the applicable transition periods for hospitals that are permitted to begin receiving incentive payments after FY 2011. Specifically, that section provides that if the "first payment year for an eligible hospital is after 2015, then the transition factor * * * for such hospital and for such year and subsequent year shall be 0." This clause in effect provides that no incentive payments will be available to a hospital that would begin to receive such payments after FY 2015. In other words, FY 2015 is the last FY in which a hospital can begin to receive incentive payments. Taken together, sections 1886(n)(2)(G)(i) and 1886(n)(2)(E)(ii) of the Act allow hospitals to begin receiving incentive payments during FYs 2011 through 2015. Section 1886(n)(2)(E)(ii) of the Act also establishes the transition periods and

factors that will be in effect for hospitals that begin to receive transition payments during FY 2014 and 2015. As discussed previously, that section states that if “the first payment year for an eligible hospital is after 2013, then the transition factor specified in this subparagraph for a payment year for such hospital is the same as the amount specified in clause (i) for such payment year for an eligible hospital for which the first payment year is 2013.” Section 1886(n)(2)(E)(ii) of the Act also establishes the transition periods that will be in effect for hospitals that begin to receive transition payments during FYs 2014 through 2015. That section states that if “the first payment year for an eligible hospital is after 2013, then the transition factor specified in this subparagraph for a payment year for such hospital is the same as the amount specified in clause (i) for such payment year for an eligible hospital for which

the first payment year is 2013.” By implication, this clause establishes that, for hospitals that begin to receive incentive payments in FYs 2012 and 2013, the transition periods are equivalent to those for hospitals that begin to receive such payments in FY 2011. An eligible hospital that is a meaningful user of certified EHR technology could receive incentive payments beginning with FY 2012 (transition factor equals 1), and for FY 2013 (transition factor equals three-fourths), FY 2014 (transition factor equals one-half), and FY 2015 (transition factor equals one-fourth). Similarly, an eligible hospital that is a meaningful EHR user could receive incentive payments beginning with FY 2013 (transition factor equals 1), and for FYs 2014 (transition factor equals $\frac{3}{4}$), 2015 (transition factor equals $\frac{1}{2}$), and 2016 (transition factor equals $\frac{1}{4}$).

However, this section also specifically provides that the transition factor is

modified for those eligible hospitals that first become meaningful users of certified EHR technology beginning in 2014 or 2015. Such hospitals would receive payments as if they became meaningful EHR users beginning in 2013. In other words, if a hospital were to begin to demonstrate meaningful use of EHR certified technology in 2014, the transition factor used for that year (2014) would be $\frac{3}{4}$ instead of 1, $\frac{1}{2}$ for the second year (2015), $\frac{1}{4}$ for the third year (2016), and zero thereafter. Similarly, if a hospital were to begin meaningful use of certified EHR technology in 2015, the transition factor used for that year would be $\frac{1}{2}$ instead of 1, $\frac{1}{4}$ for the second year (2016), and zero thereafter.

Table 25 shows the possible years an eligible hospital could receive an incentive payment and the transition factor applicable to each year.

TABLE 25—TRANSACTION FACTOR FOR MEDICARE FFS ELIGIBLE HOSPITALS

Fiscal year	Fiscal year that eligible hospital first receives the incentive payment				
	2011	2012	2013	2014	2015
2011	1.00
2012	0.75	1.00
2013	0.50	0.75	1.00
2014	0.25	0.50	0.75	0.75
2015	0.25	0.50	0.50	0.50
2016	0.25	0.25	0.25

We welcome comments from the public on our discussion of these statutory requirements regarding the computation of the incentive payment amounts, and the issues regarding the sources and timing of data for use in these computations.

g. Incentive Payment Adjustment Effective in FY 2015 and Subsequent Years for Eligible Hospitals Who Are Not Meaningful EHR Users

In addition to providing for incentive payments for meaningful use of EHRs during a transition period, section 1886(b)(3)(B) of the Act, as amended by section 4102(b)(1) of the HITECH Act, provides for an adjustment to the market basket 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, section 1886(b)(3)(B) 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.” For FY 2015 and each subsequent FY, the reduction to three-quarters of the applicable update for an eligible hospital that is not a meaningful EHR user will be “33 $\frac{1}{3}$ percent for FY 2015, 66 $\frac{2}{3}$ percent for FY 2016, and 100 percent for FY 2017 and each subsequent FY.” In other words, the Secretary is required to subject eligible hospitals who are not meaningful users to one-quarter, one-half, and three-quarters reductions of their market basket updates in FY 2015, FY 2016, and FY 2017 and subsequent years respectively. 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.” This provision establishes a continuing incentive for hospitals to become meaningful EHR users, because a hospital that does become a meaningful EHR user in any year after the effective date of the

update reduction will receive the same, fully updated standardized amount for that year, and subsequent years, as those hospitals that were already meaningful EHR users at the time when the update reduction went into effect (although hospitals would remain subject to a separate reduction for failure to report quality data under RHQDAPU). In order to conform with this new update reduction, section 4102(b)(1)(A) of the HITECH Act revises section 1886(b)(3)(B)(viii)(1) of the Act 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 market basket update. In this way, even the combined reductions 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 market basket remains a positive number.

The following example illustrates how this payment reduction would work. Suppose that the market basket “percentage increase otherwise applicable” to the IPPS standardized

amount is 2.0 percent. Of this 2.0 percent, one-quarter (0.5 percent) of the market basket update would be subject to a reduction for any hospital that fails to submit data on quality measures, and up to three-quarters (1.5 percent) would be subject to a reduction for any hospital that is not a meaningful EHR user. For FY 2015, hospitals could receive one of four different updates, depending upon their reporting of quality data and their use of EHRs:

- A hospital that reports quality data and qualifies as a meaningful EHR user would receive the full update of 2.0 percent.
- A hospital that fails to report quality data but is a meaningful EHR user would receive an update of 1.5 percent, which represents the full 2.0 percent update minus the reduction of one-quarter (0.5 percentage point) for failing to report quality data.
- A hospital that reports quality data but does not qualify as a meaningful EHR user would receive an update of 1.5 percent, which represents the full 2.0 percent update minus 0.5 percentage point (33⅓ percent of three-quarters of the full update: $\frac{1}{3}$ times 1.5 equals 0.5).
- A hospital that fails to report quality data and does not qualify as a meaningful EHR user would receive an update of 1.0 percent, which represents the full 2.0 percent update minus the reduction of one-quarter (0.5 percentage point) for failing to report quality data, and a further reduction of 0.5 percentage point (33⅓ percent of three-quarters of the full update: $\frac{1}{3}$ times 1.5 equals 0.5).

For FY 2016, hospitals could receive one of four different updates (assuming a 2 percent update that is otherwise applicable), depending upon their reporting of quality data and their use of EHRs:

- A hospital that reports quality data and qualifies as a meaningful EHR user would receive the full update of 2.0 percent.
- A hospital that fails to report quality data, but is a meaningful EHR user would receive an update of 1.5 percent, which represents the full 2.0 percent update minus the reduction of one-quarter (0.5 percentage point) for failing to report quality data.
- A hospital that reports quality data, but does not qualify as a meaningful EHR user would receive an update of 1.0 percent, which represents the full 2.0 percent update minus 1.0 percentage point (66⅔ percent of three-quarters of the full update: $\frac{2}{3}$ times 1.5 equals 1.0).
- A hospital that fails to report quality data, and does not qualify as a meaningful EHR user would receive an update of 0.5 percent, which represents

the full 2.0 percent update minus the reduction of one-quarter (0.5 percentage point) for failing to report quality data, and a further reduction of 1.0 percentage point (66⅔ percent of three-quarters of the full update: $\frac{2}{3}$ times 1.5 equals 1.0).

For FYs 2017 and subsequent FYs, the possibilities (assuming a 2 percent update that is otherwise applicable) are as follows:

- A hospital that reports quality data and qualifies as a meaningful EHR user would receive the full update of 2.0 percent.
- A hospital that fails to report quality data, but is a meaningful EHR user would receive an update of 1.5 percent, which represents the full 2.0 percent update minus the reduction of one-quarter (0.5 percentage point) for failing to report quality data.
- A hospital that reports quality data, but does not qualify as a meaningful EHR user would receive an update of 0.5 percent, which represents the full 2.0 percent update minus 1.5 percentage points (100 percent of three-quarters of the full update, which equals 1.5) for failing to be a meaningful EHR user.
- A hospital that fails to report quality data, and does not qualify as a meaningful EHR user would receive an update of 0.0 percent, which represents the full 2.0 percent update minus the reduction of one-quarter (0.5 percentage point) for failing to report quality data, and a further reduction of 1.5 percentage points (100 percent of three-quarters of the full update, which equals 1.5) for failing to be a meaningful EHR user.

These examples are illustrative of current law. Specific proposals to implement these payment adjustments for subsection (d) hospitals that are not meaningful EHR users are not being made at this time but will be subject to future rule-making prior to the 2015 implementation date. We welcome comments on these payment adjustments and any comments received will be considered in developing future proposals to implement these provisions.

3. Incentive Payments for Critical Access Hospitals (CAHs)

Section 1814(l)(3)(A) of the Act, as amended by section 4102(a)(2) of the HITECH Act, also provides for incentive payments for CAHs that are meaningful users of certified EHR technology during an EHR reporting period for a cost reporting period beginning during a payment year after FY 2010 but before FY 2016. The criteria for being a meaningful EHR user, and the manner for demonstrating meaningful use, are

discussed in section II.A.2. of this proposed rule.

a. Definition of CAHs for Medicare

Section 1861(mm)(1) of the Act defines a CAH as a facility that has been certified as a critical access hospital under section 1820(c). CAHs are reimbursed for services furnished to Medicare beneficiaries under section 1814(l) of the Act for inpatient services and section 1834(g) of the Act for outpatient services. Incentive payments for CAHs under section 1814(l)(3)(A) of the Act will be calculated based on the provider number used for cost reporting purposes, which is the CCN of the main provider. The process for making incentive payments to CAHs is discussed in section II.B.4.c. of this proposed rule.

b. Current Medicare Payment of Reasonable Cost for CAHs

For Medicare purposes, CAHs are paid for most inpatient and outpatient services to Medicare beneficiaries on the basis of reasonable cost under section 1814(l) and section 1834(g) of the Act, respectively. Thus, CAHs are not subject to the IPPS and Hospital Outpatient Prospective Payment System (OPPS).

Section 1861(v)(1)(A) of the Act is the statutory basis for reasonable cost reimbursement in Medicare. Under the reasonable cost reimbursement methodology, payments to providers are based on the reasonable cost of furnishing Medicare-covered services to beneficiaries. Reasonable cost includes all necessary and proper costs in furnishing the services, subject to the principles of reasonable cost reimbursement relating to certain specific items of revenue and cost. Reasonable cost takes into account both direct and indirect costs of providers of services, including normal standby costs. The objective of the reasonable cost methodology is to ensure that the costs for individuals covered by the program are not borne by others not so covered, and the costs for individuals not so covered are not borne by the program. The reasonable costs of services and the items to be included are determined in accordance with the regulations at 42 CFR part 413, manual guidance, and other CMS instructions.

Currently, under section 1814(l)(1) of the Act and § 413.70(a) of the regulations, effective for cost reporting periods beginning on or after January 1, 2004, payment for inpatient services of a CAH, other than services of a distinct part unit of a CAH, is 101 percent of the reasonable costs of the CAH in providing CAH services to its inpatients, as determined in accordance with

section 1861(v)(1)(A) of the Act and with the applicable principles of cost reimbursement in Parts 413 and 415 of the regulations. However, payment for inpatient CAH services is not subject to the reasonable cost principles of the lesser of cost or charges, the reasonable compensation equivalent limits for physician services to providers, the ceilings on hospital operating costs, and the payment window provisions for preadmission services, specified in § 412.2(c)(5) and § 413.40(c)(2). Section 1834(g) of the Act and § 413.70(b) of the regulations describe the payment methodology for outpatient services furnished by a CAH.

Currently, reasonable cost reimbursement for CAHs includes payment for depreciation of depreciable assets used in providing covered services to beneficiaries, as described under Part 413 subpart G of our regulations and § 104 of the Medicare Provider Reimbursement Manual (PRM). In general, the depreciation expense of an asset, representing a portion of the depreciable asset's costs which is allocable to a period of operation, is determined by distributing the acquisition costs of the depreciable asset, less any salvage costs, over the estimated useful life of the asset.

c. Changes Made by the HITECH Act

Sections 4102(a)(2) and 4102(b)(2) of the HITECH Act amended section 1814(l) of the Act, which governs payment for inpatient CAH services. The HITECH Act did not amend section 1834(g) of the Act, which governs payment for outpatient CAH services.

Sections 4102(a)(2) and 4102(b)(2) of the HITECH Act amended section 1814(l) of the Act by adding new paragraphs (3), (4), and (5) as follows:

Section 1814(l)(3)(A) of the Act provides the following:

The following rules shall apply in determining payment and reasonable costs * * * for a critical access hospital that would be a meaningful EHR user (as would be determined under paragraph (3) of section 1886(n)) for an EHR reporting period for a cost reporting period beginning during a payment year if such critical access hospital was treated as an eligible hospital under such section:

(i) The Secretary shall compute reasonable costs by expensing such costs in a single payment year and not depreciating these costs over a period of years (and shall include as costs with respect to cost reporting periods beginning during a payment year costs from previous cost reporting periods to the extent they have not been fully depreciated as of the period involved).

(ii) There shall be substituted for the Medicare share that would otherwise be applied [to CAHs under section 1814(l)(1)] a

percent (not to exceed 100 percent) equal to the sum of—

(I) the Medicare share (as would be specified under paragraph (2)(D) of section 1886(n)) for such critical access hospital if such critical access hospital was treated as an eligible hospital under such section; and

(II) 20 percentage points.

Section 1814(l)(3)(B) of the Act provides that the incentive payment for CAHs will be paid “through a prompt interim payment (subject to reconciliation) after submission and review of such information (as specified by the Secretary) necessary to make such payment.” The provision also states that “[i]n no case may payment under this paragraph be made with respect to a cost reporting period beginning during a payment year after 2015 and in no case may a critical access hospital receive payment under this paragraph with respect to more than 4 consecutive payment years.”

Section 1814(l)(3)(C) of the Act provides that the reasonable costs for which a CAH may receive an incentive payment are costs for the purchase of certified EHR technology to which purchase depreciation (excluding interest) would otherwise apply under section 1814(l)(1) of the Act.

Section 1814(l)(4)(A) of the Act provides for an adjustment, subject to the hardship exemption in section 1814(l)(4)(C) of the Act, to a CAH's reimbursement at 101 percent of its reasonable costs if the CAH has not met the meaningful EHR user definition for an EHR reporting period that begins in FY 2015 or a subsequent fiscal year. Section 1814(l)(4)(B) of the Act specifies that if a CAH is not a meaningful EHR user during the cost reporting period beginning in FY 2015, its reimbursement will be reduced from 101 percent of its reasonable costs to 100.66 percent. For FY 2016, the percentage of reimbursement for a CAH that is not a meaningful EHR user is reduced to 100.33 percent of its reasonable costs. For FY 2017 and each subsequent FY, the percentage of reimbursement is reduced to 100 percent of reasonable costs. Section 1814(l)(4)(C) of the Act states that, as provided for eligible subsection (d) hospitals, the Secretary may, on a case-by-case basis, exempt a CAH from this adjustment if the Secretary determines, subject to annual renewal, that requiring the CAH to be a meaningful EHR user during a cost reporting period beginning in FY 2015 or a subsequent fiscal year would result in a significant hardship, 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 exemption under this provision for more than 5 years.

Section 1814(l)(5) provides that there shall be no administrative or judicial review under sections 1869 or 1878 of the Act, or otherwise, of: (1) The methodology and standards for determining the amount of payment under section 1813(l)(3) and payment adjustments under section 1814(l)(4); (2) the methodology and standards for determining a CAH to be a meaningful EHR user; (3) the methodology and standards for determining if the hardship exemption applies to a CAH; (4) the specification of EHR reporting periods; and (5) the identification of reasonable costs used to compute CAH incentive payments.

d. Incentive Payment Calculation for CAHs

Consistent with section 1814(l)(3)(A) of the Act, we are proposing to amend § 413.70(a) to add a new paragraph (5) to provide for an incentive payment to a qualifying CAH for the reasonable costs incurred for the purchase of certified EHR technology in a cost reporting period beginning during a payment year after FY 2010 but before FY 2016. We are proposing to include a cross-reference to § 495.106 which defines the terms associated with the CAH incentive payment, including the definition of a “qualifying CAH” that is eligible to receive the CAH incentive payment, and the methodology for determining the amount of that incentive payment. In addition, we are proposing to amend § 413.70(a) to add a new paragraph (6) to provide for the adjustment of a CAH's reasonable costs of providing inpatient services starting in FY 2015 if the CAH is not a qualifying CAH.

In computing the CAH incentive payment and applying the adjustments to a CAH's payment if the CAH is not a qualifying CAH, we propose to apply the definitions of certified EHR technology, EHR reporting period, meaningful EHR user and qualified EHR in proposed § 495.4 that are discussed elsewhere in this proposed rule.

In proposed § 495.106(a), we are proposing to define a qualifying CAH as a CAH that meets the meaningful EHR user definition for eligible hospitals in § 495.4, which is discussed in section II A.1. of this proposed rule. Also in proposed § 495.106(a), for the purposes of computing the CAH incentive payment, we are proposing that the reasonable costs for the purchase of certified EHR technology mean the reasonable acquisition costs, excluding any depreciation and interest expenses associated with the acquisition,

incurred for the purchase of depreciable assets as described at part 413 subpart G, such as computers and associated hardware and software, necessary to administer certified EHR technology as defined in § 495.4 of this proposed rule. We also propose to define payment year for CAHs to mean a fiscal year beginning after FY 2010 but before FY 2016.

Under proposed § 495.106(b), we specify that a qualifying CAH shall receive an incentive payment for its reasonable costs incurred for the purchase of certified EHR technology. The CAH incentive payment will be for a cost reporting period that begins during a payment year after FY 2010 but before FY 2016.

Consistent with section 1814(l)(3)(A) of the Act, under proposed § 495.106(c), the proposed payment methodology for computing the incentive payment for a qualifying CAH for a cost reporting period during a payment year is equal to the product of—(1) the reasonable costs incurred for the purchase of certified EHR technology in that cost reporting period and any similarly incurred costs from previous cost reporting periods to the extent they have not been fully depreciated as of the cost reporting period involved and (2) the CAH's Medicare share which equals the Medicare share as computed for eligible hospitals including the adjustment for charity care (described in sections II.A.2.b. and A.3. of this proposed rule) plus 20 percentage points. However, in no case will the resulting Medicare share for a CAH exceed 100 percent. This percentage adjustment will be used in place of the 101 percent typically applied to a CAH's reasonable costs under section 1814(l)(1) of the Act and § 413.70(a) of the regulations.

For example, a CAH first requests an incentive payment for its cost reporting period beginning on January 1, 2012 which is in FY 2012. The CAH incurred reasonable costs of \$500,000 for the purchase of certified EHR technology in its previous cost reporting period beginning on January 1, 2011. This CAH is a meaningful user of certified EHR technology during the relevant EHR reporting period and thus qualifies for an incentive payment for FY 2012. (For illustrative purposes this example assumes no salvage value of the assets acquired.) The CAH depreciated \$100,000 of the costs of these items in the cost reporting period beginning on January 1, 2011. As a result, the amount used to compute the incentive payment will be the remaining \$400,000 of undepreciated costs. The CAH's Medicare share is 90 percent (its Medicare share of 70 percent using the

methodology described in section II.A.2.b. of this proposed rule plus 20 percentage points). Therefore, the CAH's incentive payment for FY 2012 is \$360,000 (\$400,000 times 90 percent). This CAH's first payment year is FY 2012, and it can receive incentive payments through 4 consecutive payment years which, in this example, would be FYs 2012 through 2015.

If, in the above example, the CAH also incurred reasonable costs of \$300,000 for the purchase of certified EHR technology in its cost reporting period beginning in FY 2012 that will not be depreciated, then the incentive payment for FY 2012 is \$630,000 (\$700,000 (\$400,000 in FY 2011 plus \$300,000 in FY 2012) times 90 percent).

(The preceding examples are offered for illustrative purposes only and are not intended to encompass all possible computations of the CAH incentive payment.)

Under proposed § 495.106(d)(1), the amount of the incentive payment made to a qualifying CAH under this section represents the expensing and payment of the reasonable costs of certified EHR technology computed as described above in a single payment year and, as specified in § 413.70(a)(5), such payment is made in lieu of any payment that would have been made under § 413.70(a)(1) for the reasonable costs of the purchase of certified EHR technology including depreciation and interest expenses associated with the acquisition. The Medicare contractor will review the CAH's current year and each subsequent year's cost report to ensure that the assets associated with the acquisition of certified EHR technology are expensed in a single period and that depreciation and interest expenses associated with the acquisition are not allowed.

Under proposed § 495.106(d)(2), the amount of the incentive payment made to a qualifying CAH under this section is paid through a prompt interim payment for the applicable payment year after—(1) The CAH submits the necessary documentation, as specified by CMS or its Medicare contractor, to support the computation of the incentive payment amount; and (2) CMS or its Medicare contractor reviews such documentation and determines the interim amount of the incentive payment.

Under § 495.106(d)(3), the interim incentive payment is subject to a reconciliation process as specified by CMS and the final incentive payment as determined by CMS or its Medicare contractor is considered payment in full for the reasonable costs incurred for the

purchase of certified EHR technology in a payment year.

Under § 495.106(d)(4), we propose that an incentive payment may be made with respect to a cost reporting period beginning during a payment year beginning with FY 2011 (October 1, 2010 through September 30, 2011) through FY 2015 (October 1, 2014 through September 30, 2015), but in no case may a CAH receive an incentive payment with respect to more than four consecutive payment years. Therefore, a CAH, that is a meaningful EHR user, may begin receiving an incentive payment for its cost reporting period beginning in FY 2011 for the incurred reasonable costs for the purchase of certified EHR technology during that cost reporting period and in previous cost reporting periods to the extent that the item or items have not been fully depreciated. These incentive payments will continue for no more than 4 consecutive payment years and will not be made for a cost reporting period beginning during a payment year after 2015. As discussed in section II.B.4. of this proposed rule, the CAH must submit supporting documentation for its incurred costs of purchasing certified EHR technology to its Medicare contractor (Fiscal Intermediary (FI)/MAC).

CAHs cannot receive an incentive payment for a cost reporting period that begins in a payment year after FY 2015. If the first payment year for a CAH is FY 2013 then the fourth consecutive payment year would be 2016. However, the CAH cannot be paid an incentive payment for FYs 2016 and beyond. For FY 2016 and beyond, payment to CAHs for the purchase of additional EHR technology will be made under § 413.70(a)(1) in accordance with the reasonable cost principles, as described above, which would include the depreciation and interest cost associated with such purchase.

e. Reduction of Reasonable Cost Payment 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) to include an adjustment to a CAH's reimbursement at 101 percent of its reasonable costs if the CAH has not met the meaningful EHR user definition for an EHR reporting period that begins in FY 2015, FY 2016, FY 2017, and each subsequent FY thereafter. Consistent with this provision, under proposed § 495.106(e) and § 413.70(a)(6), if a CAH has not demonstrated meaningful use of certified EHR technology for FY 2015, its reimbursement will be reduced from

101 percent of its reasonable costs to 100.66 percent. For FY 2016, its reimbursement will be reduced to 100.33 percent of its reasonable costs. For FY 2017 and each subsequent FY, its reimbursement will be reduced to 100 percent of reasonable costs.

However, as provided for eligible hospitals, a CAH may, on a case-by-case basis, be exempted from this adjustment if CMS or its Medicare contractor determines, on an annual basis, that requiring the CAH to be a meaningful EHR user would result in a significant hardship, 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 exemption under this provision for more than 5 years.

Section 1814(l)(5) of the Act exempts the determinations made under paragraphs (l)(3) and (l)(4) from administrative and judicial review. Accordingly, under proposed § 413.70(a)(6)(iv) and § 495.106(f), we are proposing that there shall be no administrative or judicial review under sections 1869 or 1878 of the Act, or otherwise, of the following:

- The methodology and standards for determining the amount of payment under section 1814(l)(3) of the Act and payment adjustments under section 1814(l)(4) of the Act for CAHs, including selection of periods under section 1886(n)(2) of the Act for determining, and making estimates or using proxies of, inpatient-bed-days, hospital charges, charity charges, and the Medicare share under subparagraph (D) of section 1886(n)(2) of the Act;
- The methodology and standards for determining a CAH to be a meaningful EHR user under section 1886(n)(3) of the Act as would apply if the CAH was treated as an eligible hospital under section 1886(n) of the Act;
- The methodology and standards for determining if the hardship exemption under section 1814(l)(4)(C) of the Act applies to a CAH;
- The specification of EHR reporting periods under section 1886(n)(6)(B) of the Act as applied under section 1814(l)(3) and (4) of the Act for CAHs; and
- The identification of reasonable costs used to compute the CAH incentive payment under section 1814(l)(3)(C) of the Act.

4. Process for Making Incentive Payments Under the Medicare FFS Program

As previously discussed in section II.B.1. and 2. of this proposed rule and sections 1848(o)(1) and 1886(n)(1) of the Act, the statute provides for incentive

payments to eligible professionals, eligible hospitals, and CAHS who are meaningful users of certified EHR technology as early as FY 2011 for qualifying eligible hospitals and CAHs and CY 2011 for qualifying EPs. The statute does not specify the process for making these payments to qualifying EPs and qualifying eligible hospitals and CAHs participating in the FFS Medicare incentive payment program, but instead leaves the payment process to the Secretary's discretion.

We propose that FIs, carriers, and MACs, as appropriate, would be responsible for determining the incentive payment amounts for qualifying EPs and qualifying eligible hospitals and CAHs in accordance with the proposed methodology set forth in section II.B.1.b. and B.2.b. of this proposed rule based on the previously discussed meaningful use criteria, disbursing the incentive payments to qualifying EPs and qualifying eligible hospitals and CAHs, and resolving any reconciliation issues.

a. Incentive Payments to EPs

We propose that the carriers/MACs calculate incentive payment amounts for qualifying EPs. Incentive payments will be disbursed on a rolling basis, as soon as they ascertain that an EP has demonstrated meaningful use for the applicable reporting period (i.e., 90 days for the first year or a calendar year for subsequent years), and reached the threshold for maximum payment. As discussed previously in section II.A.1.b. of this proposed rule, once a qualifying EP's allowed charges reach the minimum threshold of allowed charges for the payment year, the qualifying EP is eligible to receive the maximum incentive payment; the carrier/MAC would be authorized to disburse the full incentive payment to that qualifying EP. If a qualifying EP's allowed charges do not reach the minimum threshold during the payment year (including subsequent claims submitted not later than 2 months after the end of the payment year per statute) and if the qualifying EP is also a qualifying MA EP, the qualifying MA organization with which the EP is affiliated will receive the incentive payment for the EP from the MA. If the qualifying EP does not also qualify as a MA EP, then the carriers/MAC will calculate the amount of the qualifying EP's incentive payment an amount determined by statute as 75 percent of the accumulated allowed charges based on claims submitted not later than 2 months after the end of the payment year), and disburse the incentive payment to the qualifying EP in the year following payment year. The

carriers/MACs will issue incentive payments to qualifying EPs after ensuring payment has not already been made under the Medicaid program for the relevant payment year. As required by section 1848(m)(2) of the Act as amended by section 4101(f) of the HITECH Act, qualifying EPs receiving incentive payments from the Medicare EHR incentive payment program may not also receive an e-prescribing incentive payment. The carriers/MACs will also track the incentive payment at the qualifying EP's TIN level, and disburse the electronic payment to the TIN provided by the qualifying EP indicated during the registration process; qualifying EPs who do not have individual TINs (that is, a qualifying EP who works solely in a group practice) will be paid at the group practice level's TIN. Since some EPs work in multiple group practices, we considered allowing these EPs to direct that their incentive payment be allocated among the multiple practices based on individual and/or group TINs. However, as discussed more fully in section II.B.1.d of this proposed rule, we determined that this would create a significant administrative burden for us and therefore are proposing that qualifying EPs select one TIN for disbursement of their Medicare EHR incentive payment. Of course, after the payment is disbursed to their designated TIN, qualifying EPs may decide to allocate their incentive payment among the multiple practices in which they furnish covered professional services, subject to applicable laws, regulations and rules, including, without limitation, those related to fraud, waste, and abuse.

In addition, we recognize that financial relationships between physicians and their employers/entities with which they have contractual arrangements may implicate certain fraud, waste, and abuse laws, regulations, and rules. Therefore, we are considering including specific safeguards to limit the risk that the allocation/reassignment of incentive payments could raise under those and other applicable laws, regulations and rules; we appreciate public comments on this consideration.

b. Incentive Payments to Eligible Hospitals

The FIs/MACs will calculate incentive payments for qualifying eligible hospitals, and will disburse such payments on an interim basis once the hospital has demonstrated it is a meaningful EHR user for the EHR reporting period for the payment year. As discussed above in section B.2.b. of the proposed rule, the formula for

calculating a qualifying eligible hospital's incentive payment requires the following data: (1) An initial amount; (2) the Medicare share; and (3) a transition factor applicable to that payment year. FIs/MACs will use the prior-year cost report, Provider Statistical and Reimbursement (PS&R) System data, and other estimates to calculate the interim incentive payment. As discussed in section II.B.2.c. of this proposed rule, beginning in 2010, cost reports will capture charity care data which will be used in calculating the Medicare share of the payment. As discussed in section II.B.2.b. of this proposed rule, we are proposing to calculate a qualifying hospital's final incentive payment using data from the cost report for the hospital's fiscal year that ends during the FY prior to the FY that serves as the payment year. We therefore are proposing that the FIs/MACs calculate the final incentive payment using actual cost report data for the hospital's fiscal year that ends during the FY prior to the fiscal year that serves as the payment year, and will reconcile the incentive payment as necessary at settlement of the cost report. Incentive payments for qualifying eligible hospitals will be calculated based on the provider number used for cost reporting purposes, which is the CCN of the main provider. Therefore, the FIs/MACs would disburse incentive payments to qualifying hospitals based on the CCN rather than the TIN.

c. Incentive Payments to CAHs

CAHs are paid on a cost reimbursement basis; once a CAH incurs actual EHR costs, it can submit supporting documentation to the FI/MAC for review. The FIs/MACs will determine an incentive payment amount, as previously discussed in section II.A.3. of this proposed rule by substituting for the Medicare share amount that would otherwise be applied under the formula used for computing payments for eligible hospitals, a percent (not to exceed 100 percent) equal to the sum of—(1) The Medicare share for such CAH, and (2) 20 percentage points.

The FIs/MACs will reconcile the cost report and ensure the EHR expenses are adjusted on the cost report to avoid duplicate payments. Incentive payments for qualifying CAHs will be calculated based on the provider number used for cost reporting purposes, which is the CCN number of the main provider. Therefore, the FIs/MACs will disburse incentive payments to qualifying CAHs based on the CCN number rather than the TIN.

d. Payment Accounting Under Medicare

We will conduct selected compliance reviews of EPs, eligible hospitals, and qualified CAHs who register for the incentive programs and of recipients of incentive payments for the meaningful use of certified EHR technology. The reviews will validate provider eligibility and their meaningful use attestations including verification of meaningful use and would also review components of the payment formulas.

We will identify and recoup overpayments made under the incentive payment programs that result from incorrect or fraudulent attestations, quality measures, cost data, patient data, or any other submission required to establish eligibility or to qualify for a payment. The overpayment will be recouped by CMS or its agents from the EP, eligible hospital, MA organization, CAH, other entities to whom the right to payment has been assigned/reassigned, or, in the case of Medicaid, from the State Medicaid agencies. Medicare FFS EPs and eligible hospitals will need to maintain evidence of qualification to receive incentive payments for 10 years after the date they register for the incentive program.

C. Medicare Advantage (MA) Organization Incentive Payments

1. Definitions

a. Qualifying MA Organization

Section 1853(l)(1) of the Act, as added by section 4101(c) of the HITECH Act, provides for incentive payments to qualifying MA organizations for certain of their affiliated EPs who are meaningful users of certified EHR technology during the relevant EHR reporting period for a payment year. Section 1853(l)(5) of the Act defines the term “qualifying MA organization” as an MA organization that is organized as a health maintenance organization (HMO) as defined in section 2791(b)(3) of the PHS Act. Section 2791(b)(3) of the PHS Act in turn defines a health maintenance organization as a federally qualified HMO, an organization recognized as an HMO under State law, or a similar organization regulated for solvency under State law in the same manner and to the same extent as an HMO. Since there are few federally qualified HMOs, we expect MA organizations to primarily qualify for incentive payments as State-licensed HMOs, or as organizations regulated for solvency under State law in the same manner and to the same extent as HMOs. Therefore, in § 495.200 we propose to define “qualifying MA organization.”

In § 495.202(a)(2), we propose to deem MA organizations offering MA HMO plans that are not federally-qualified HMOs to meet the definition of HMO in section 2791(b)(3) of the PHS Act, as HMOs recognized under State law, or as entities subject to State solvency rules in the same manner as HMOs. We believe this is reasonable because under the MA application process, State regulators are required to certify that MA organizations operating in their State are authorized to offer the type of MA plan they propose to offer, and meet solvency standards that are adequate for these purposes. For each MA organization offering MA HMO plans, the State has thus recognized that the organization is able to assume risk as an HMO. Therefore, we have determined that absent evidence to the contrary, an MA organization offering HMO plans is recognized by the State as a health maintenance organization, or that it is subject to State solvency standards in the same manner and to the same extent as an HMO and therefore provides sufficient assurance that the section 2791(b)(3) of the PHS Act definition is met.

In proposed § 495.202(a)(3), for MA organizations that offer other coordinated care MA plans (Preferred Provider Organization (PPO) plans, Provider Sponsored Organization (PSO) plans, and Regional Preferred Provider Organization (RPPO) plans) and for other MA organizations offering other MA plan types (private fee-for-service (PFFS) plans, Medical Savings Account (MSA) plans), we would require the sponsoring MA organization to attest that the MA organization is recognized under State law as an HMO, or that it is a similar organization regulated under State law for solvency in the same manner and to the same extent as an HMO before we would make a determination that the MA organization is a qualifying MA organization for purposes of incentive payments.

b. Qualifying MA Eligible Professional (EP)

A qualifying MA organization may receive an incentive payment only for those EPs described under section 1853(l)(2) of the Act, as added by section 4101(c) of the HITECH Act. Section 1853(l)(2) of the Act provides that these EPs must be “eligible professionals” as defined under section 1848(o) of the Act as added by section 4101(a) of the HITECH Act, and must either—

- Be employed by the qualifying MA organization; or
- Be employed by, or be a partner of, an entity that through contract with the

qualifying MA organization furnishes at least 80 percent of the entity's Medicare patient care services to enrollees of the qualifying MA organization.

Further, the EP must furnish at least 80 percent of his or her professional services covered under Title XVIII (Medicare) to enrollees of the qualifying MA organization and must furnish, on average, at least 20 hours per week of patient care services.

As discussed in section II.A.1. of this proposed rule, an EP is defined as a physician (under section 1861(r) of the Act).

We interpret "employed by" to mean that the EP is considered an employee of a qualifying MA organization or qualifying entity under the usual common law rules applicable in determining the employer-employee relationship under section 3121(d)(2) of the Internal Revenue Code of 1986.

We interpret "to be a partner of" to mean that the qualifying MA EP has an ownership stake in the entity. Under this proposed interpretation, a professional that contracts with an entity, but has no ownership stake in the entity, would not be considered a qualifying MA EP.

We interpret "furnishing at least 80 percent" of the entity's "patient care services" to mean at least 80 percent of the qualifying MA EP's total Medicare revenue in a year (that is, total revenue from Medicare FFS as well as from all MA organizations) must be from a single qualifying MA organization.

We propose to interpret the requirement that a qualifying MA EP furnish at least 80 percent of their professional services covered under Title XVIII means that at least 80 percent of the professional's total Medicare revenue in a year (that is, total revenue from Medicare FFS as well as from all MA organizations) must be from a single qualifying MA organization. We believe that in establishing the rule that qualifying MA EPs need to furnish at least 80 percent of the EP's Title XVIII covered services "to enrollees of the organization," the statute limits payment related to any specific qualifying MA EP to a single qualifying MA organization. Thus, if a qualifying MA EP provided an average of 20 hours per week of patient care services to two distinct qualifying MA organizations, we would pay the qualifying MA organization for the MA EP only if such a qualifying EP provided at least 80 percent of his or her professional services covered under Title XVIII to enrollees of that organization.

For purposes of determining whether a qualifying MA EP furnishes, on

average, at least 20 hours per week of patient care services, we interpret the requirement to include both Medicare and non-Medicare patient care services. Moreover, we propose that the relevant time period for determining whether an MA EP furnishes at least 20 hours per week of patient care services should be the EHR reporting period. (We discuss the proposed definition of EHR reporting period in section II.A. 1. e. of this proposed rule.) Therefore, over the EHR reporting period, the qualifying EP must provide on average 20 hours per week of patient care services. Finally, we interpret "patient care services" to mean services that would be considered "covered professional services" under sections 1848(o)(5)(A) and (k)(3) of the Act. That is, health care services for which payment would be made under, or for which payment would be based on, the fee schedule established under Medicare Part B if they were furnished by an eligible professional.

We considered various methods of determining when at least 20 hours per week, on average, of patient care services will be considered to be provided by MA EPs. We considered methods such as defining a dollar or service threshold, or the number of hours of direct patient care services actually provided. After due consideration we propose to require qualifying MA organizations to attest to the fact that MA EPs for whom they are requesting EHR incentive payments have provided, on average, 20 hours of patient care services during the EHR reporting period.

As discussed in section II.B. of this proposed rule relating to Medicare FFS EPs, a qualifying MA EP is also defined as a physician under section 1861(r) of the Act. Section 1853(l)(1) of the Act, as added by section 4101(c) of the HITECH Act, provides that the provisions of sections 1848(o) and 1848(a)(7) of the Act, as amended and added by sections 4101(a) and (b) of the HITECH Act, respectively, which establish the incentive payments for EPs under Medicare FFS, apply to a qualifying MA organization's qualifying MA EPs "in a similar manner" as they apply to EPs under Medicare FFS. As discussed above in section II.A.6. of this proposed rule, section 1848(o)(1)(C)(i) of the Act, as added by section 4101(a) of the HITECH Act, states that hospital-based EPs are not eligible for incentive payments. Therefore, we propose that, similar to the Medicare FFS incentive program, MA incentive payments would also not be available for hospital-based EPs. We note that the hospital where a hospital-based EP provides his or her Medicare covered services would be

potentially entitled to an incentive payment either through the Medicare FFS incentive program, or through the MA-affiliated hospital EHR incentive program. Therefore, for such a hospital-based MA EP, a qualifying MA organization would be no more entitled to an MA EP incentive payment under the MA EHR incentive program than a similarly situated EP would be entitled to an incentive payment under the Medicare FFS EHR incentive program.

As discussed previously, an MA EP must either be employed by the qualifying MA organization, or be employed by, or be a partner of, an entity that through contract with the qualifying MA organization furnishes at least 80 percent of the entity's Medicare patient care services to enrollees of the qualifying MA organization. With respect to the later criteria, we do not propose to define the term "entity," but instead recognize that there exist a range of entities with which MA organizations contract for patient care services, including a physician group, an Independent Practice Association (IPA), an Exclusive Provider Organization (EPO), a Physician Hospital Organization (PHO), or Preferred Provider Organization (PPO).

Moreover, we recognize that an EP may contract with more than one such entity, and that these entities often contract with a number of MA organizations and other health care insurers. An EP also may directly contract with more than one MA organization. In general it is only when an EP is employed by a single qualifying MA organization, or is employed by or in partnership with an entity that contracts with a single qualifying MA organization that an EP can satisfy the criteria to be an MA EP.

Finally, the qualifying MA organization must attest to the fact that each MA EP is a meaningful user of certified EHR technology in accordance with proposed § 495.4. If all of these conditions are met, such an individual is identified as an MA EP. We propose to define the term "MA eligible professional (EP)" at § 495.200 as an EP who satisfies these conditions.

Section 4101(d) of the HITECH Act directs the Secretary to study and report on "nearly exclusive" physicians that primarily treat MA enrollees and that would not otherwise qualify for incentive payments under current law. This proposed rule does not address such individuals, as it is limited to codifying in regulation existing statutory language as discussed herein.

c. Qualifying MA-Affiliated Eligible Hospital

We propose to define “qualifying MA-affiliated eligible hospital” in § 495.200. A qualifying MA organization may receive an incentive payment only for a qualifying MA-affiliated eligible hospital described under section 1853(m)(2) of the Act, as added by section 4102(c) of the HITECH Act, that is a meaningful user of certified EHR technology as defined in proposed § 495.4. Section 1853(m)(2) of the Act provides that such MA-affiliated eligible hospitals are “eligible hospitals” as defined under section 1886(n)(6) of the Act and must be under common corporate governance with a qualifying MA organization that serves individuals enrolled under MA plans offered by such organization where more than two-thirds are Medicare individuals enrolled under MA plans offered by such organization. As discussed in section II.A.1. of this proposed rule, section 1886(n)(6) of the Act, defines an “eligible hospital” as a subsection (d) hospital (as defined under section 1886(d)(1)(B) of the Act). In § 495.200, we also propose to define “under common corporate governance”, as a qualifying MA organization and a qualifying MA-affiliated eligible hospital that have a common parent corporation, that one is a subsidiary of the other, or that the organization and the hospital have a common board of directors.

Section 1853(m)(3)(B)(i) of the Act, as added by section 4101(c) of the HITECH Act, provides that if for a payment year at least one-third (33 percent) of a MA eligible hospital’s discharges (or bed-days) of Medicare patients are covered under Part A (rather than under Part C), the hospital may only receive an incentive payment under section 1886(n) of the Act—the Medicare FFS incentive program.

In § 495.200 we propose to define “inpatient-bed-days” in the same manner as that term is defined for purposes of implementing section 4201(a) of the HITECH Act in the preamble of this proposed rule. The term will be used in the same way in computing incentive payments due qualifying MA organization under the qualifying MA-affiliated eligible hospital incentive payment program.

We note that, as discussed in section II.B.2.b. of this proposed rule, under section 1886(n)(2)(D)(i)(II) of the Act, the portion of the Medicare FFS hospital incentive payment comprising the discharge related amount, or Medicare share, is based in part on the estimated number of inpatient-bed-days

attributable to individuals enrolled in MA plans under Part C. This means that hospitals that treat individuals enrolled in MA plans will receive a Medicare FFS hospital incentive payment partially based on the number of MA-enrollee bed-days. To the extent a hospital does not meet the 33 percent threshold requiring payment through the FFS Medicare EHR hospital incentive program, incentive payments can be made to a qualifying MA organization under common corporate governance to the extent other requirements of the MA EHR hospital incentive program are met. (See section II.C.3 of this proposed rule for the computation of incentive payments to qualifying MA organizations.)

Therefore, we propose to make EHR incentive payments to qualifying MA-affiliated eligible hospitals under the FFS EHR incentive program. Finally, to the extent that such data necessary to estimate the inpatient-bed-days-related incentive payment amount are not already available to us through the normal submission of hospital cost reports, we propose to require that qualifying MA organizations seeking reimbursement for qualifying MA-affiliated eligible hospitals submit similar data.

2. Identification of Qualifying MA Organizations, MA EPs, and MA-Affiliated Eligible Hospitals

In § 495.202 we propose to require MA organizations that intend to ask for reimbursement under the MA EHR incentive payment program to so indicate as part of submissions of their initial bid under section 1854(a)(1)(A) of the Act, and to attest, in some cases, that they meet the requirements of a qualifying MA organization. For MA organizations offering an MA HMO plan type, we will deem such organizations to meet the definition of HMO in 42 U.S.C. 300–gg(b)(3), (that is, section 2791(b)(3) of the PHS Act). As noted previously, for MA organizations offering plan types other than HMOs, we propose to require an attestation by the organization that the MA organization is recognized under State law as an HMO, or that it is a similar organization regulated under State law for solvency in the same manner and to the same extent as an HMO before we would make a determination that the MA organization is a qualifying MA organization for purposes of incentive payments. We propose to require this beginning with bids due in June 2010 (for plan year 2011) for MA organizations seeking reimbursement for MA EPs and MA-affiliated eligible hospitals.

We also propose requiring qualifying MA organizations, as part of their initial bids starting with plan year 2011, to make a preliminary identification of potentially qualifying MA EPs and potentially qualifying MA-affiliated eligible hospitals for which the organizations will seek EHR incentive payments.

In developing the preliminary and final lists of potentially qualifying MA EPs, qualifying MA organizations must exclude hospital-based MA EPs. We propose that qualifying MA organizations identify hospital-based MA EPs using the same criteria outlined in section II.A.6 of this proposed rule for identifying hospital-based EPs in the Medicare FFS EHR incentive program.

Along with both the preliminary and final lists of potentially qualifying MA EPs and hospitals, qualifying MA organizations must submit an attestation that these professionals and hospitals meet the criteria to be considered eligible. For example, for hospitals, the qualifying MA organization must attest that they are under common corporate governance with the qualifying MA organization. For example, for EPs, the qualifying MA organization must attest that the list does not include any hospital-based EPs.

We propose requiring qualifying MA organizations to provide final identification of potentially qualifying MA EPs by the end of the MA EP payment year (December 31), and final identification of potentially qualifying MA-affiliated eligible hospitals by the end of the MA-affiliated hospital payment year (the FFY ending on September 30), for which MA EHR incentive payments will be sought. We also propose requiring qualifying MA organizations to report the name, practice address, and other identifying information, like NPI, for all physicians that meet the requirements of a qualifying MA EP for which the qualifying MA organization will be requesting payment under the MA EHR incentive payment program.

Once a qualifying MA organization identifies potential EPs, we are required to ensure that such EPs did not receive the maximum EHR incentive payment for the relevant payment year under the Medicare FFS program under section 1848(o)(1)(A) of the Act, as added by section 4101(a) of the HITECH Act, before releasing an incentive payment to a qualifying MA organization related to such EP. (See section 1853(l)(3)(B)(i) of the Act, as added by section 4101(c) of the HITECH Act). Therefore, in order to allow us time to determine whether an MA EP received the maximum EHR incentive payment under the Medicare

FFS program, we propose not to make incentive payments to qualifying MA organizations for the MA EPs for a payment year until after the final computation of EP incentive payments for that year under the Medicare FFS program. Additionally, we propose to require qualifying MA organization to ensure that all MA EPs are enumerated through the NPI system, in order to detect and prevent duplicate payment for EPs under both the FFS and MA EHR incentive payment programs.

We also propose to require all qualifying MA organizations to self-report and identify themselves, regardless of whether they have qualifying MA EPs or MA-affiliated eligible hospitals for whom or which the organization plans to claim incentive payments at the time the initial bid is due (the first Monday of June, see section 1854(a)(1)(A) of the Act) beginning in 2014 for bids related to plan year 2015. We propose to require this reporting by all qualifying MA organizations in years beginning with 2014 in anticipation of the statutory requirement in sections 1853(l)(4) and 1853(m)(4) of the Act, to negatively adjust our capitation payments to qualifying MA organizations for MA EPs and MA-affiliated eligible hospitals that are not meaningful users of certified EHR technology for years beginning with 2015.

3. Computation of Incentives to Qualifying MA Organizations for MA EPs and Hospitals

In § 495.204, we propose a methodology under which payments to qualifying MA organizations for qualifying MA EPs will be computed. Section 1853(l)(3)(A) of the Act provides that in applying section 1848(o), instead of the additional payment amount specified under section 1848(o)(1)(A) of the Act, the Secretary may substitute an amount determined by the Secretary, to the extent feasible and practical, to be similar to the estimated amount in the aggregate that would be payable under, or would be based on, the Medicare physician fee schedule under Part B instead of Part C. Section II.B.1. of this proposed rule discusses these provisions.

Section 1853(m)(3)(A) of the Act provides that in providing an incentive payment to qualifying MA organizations for MA-affiliated hospitals, we substitute for the amount specified under section 1886(n)(2) of the Act—the incentive payment amount under Medicare FFS for qualifying eligible hospitals—an amount determined by the Secretary to be similar to the estimated amount in the aggregate that

would be payable if payment for services furnished by such hospitals was payable under Part A instead of Part C. (For more detailed information see section II.B.2. of this proposed rule.)

Section 1848(o) of the Act permits us to make the incentive payments for a year in installments, although we are proposing to make a single lump sum payment under the Medicare FFS EHR incentive program. We read the term “aggregate” to mean the aggregate installment payments made by us under the FFS EHR incentive program to a qualifying EP over the course of the relevant payment year.

The duplicate payment provisions in section 1853(l)(3)(B)(i)(II) of the Act direct us to make payment for EPs “only under” the MA EHR incentive program “and not under” the Medicare FFS EHR incentive program to the extent any EP has earned “less than [the] maximum incentive payment for the same period” under the Medicare FFS EHR incentive program. We note that section 1853(l)(1) of the Act, provides that section 1848(o) of the Act applies in a “similar,” but not the same, manner to qualifying MA organizations as it applies to EPs under Part B. The Medicare FFS incentive payment program under section 1848(o) does not include payment for professional services provided to MA enrollees, but only for services paid under Part B. In a similar manner we propose to limit payment to an MA organization to only payment for their EPs’ services to MA enrollees of plans offered by the MA organization. We do not believe it would be appropriate to provide an incentive payment to an MA organization for services provided to individuals covered under Part B. Therefore, we propose, that in calculating qualifying MA EP incentive payments, we will only consider covered professional services provided to enrollees of MA plans offered by qualifying MA organizations and will not include in the calculation any services reimbursed by Medicare FFS.

Under the Medicare FFS EHR incentive program, an EP’s incentive payment may not exceed the annual limits specified under section 1848(o)(1)(B)(i) of the Act. We propose that similar payment limits apply to qualifying MA organizations for their qualifying MA EPs. Specifically, the incentive payment to a qualifying MA organization for each of its qualifying MA EPs may not exceed certain limits. Specifically, section 1848(o)(1)(B) of the Act provides that the incentive payment for an EP for a given year shall not exceed the following amounts:

- For the EP’s first payment year, \$15,000 (or, if the first payment year is 2011 or 2012, \$18,000).
- For the EP’s second payment year, \$12,000.
- For the EP’s third payment year, \$8,000.
- For the EP’s fourth payment year, \$4,000.
- For the EP’s fifth payment year, \$2,000.
- For any succeeding year, \$0.

Note that, similar to the Medicare FFS EHR incentive program, there will be no incentive payments made with respect to a year after 2016. We propose similar restrictions related to qualifying MA organizations. So, the maximum cumulative incentive payment over 5 years to a qualifying MA organization for each of its qualifying MA EPs that meaningfully use certified EHRs beginning on or before 2012 would be \$44,000 per qualifying MA EP. For qualifying MA organizations first reporting the meaningful use of certified EHRs by qualifying MA EPs after 2014, there is no incentive payment amount available. Subject to an exception discussed below, for MA organizations first reporting the meaningful use of certified EHRs by qualifying MA EPs in 2013 or 2014, the maximum potential incentive payment per qualifying EP is, respectively, \$39,000 over 4 years, and \$24,000 over 3 years.

As we discuss in more detail in the section II.C.4. of this proposed rule, we propose to make MA EP incentive payments to qualifying MA organizations on the same payment cycle for all employed/partnering qualifying EPs of the organization. In other words, all MA EPs of a specific qualifying MA organization will be in the same payment year with respect to the amount of the incentive payment per qualifying EP that we will make. So, for instance, if a qualifying MA organization is in its second payment year in 2013 and it hires a new EP for which the qualifying MA organization had not previously received an EHR incentive payment, we will nevertheless make a second year incentive payment (up to \$12,000 in 2013) with respect to such an MA EP—assuming all other conditions are met. Thus, the limits on MA EP incentive payments discussed above are applied to the qualifying MA organization’s entire MA EP population in any specific payment year relative to that MA organization, regardless of the length of employment/partnership of/ between that specific MA EP and that specific qualifying MA organization.

Under section 1848(o)(1)(B)(iv) of the Act, the annual incentive payment limit for EPs who predominantly furnish Part

B services in a geographic health professional shortage area (HPSA) is increased by 10 percent. While we do not anticipate that MA EPs would generally practice in a HPSA area, to the extent that an MA EP practices in an area where he or she would be entitled to the 10 percent increase, that amount would apply to MA EPs as well. We explored various ways of computing the EP-level incentive payments due qualifying MA organizations whose qualifying MA EPs meaningfully use certified EHR technology.

One option that we considered was using MA plan bidding and MA payment data to estimate average annual MA revenue for qualifying MA EPs with respect to a qualifying MA organization. So, for instance, a qualifying MA organization that estimated MA Part B service-related physician costs of \$3 million/year in its bid for a year, and that employed 100 qualifying MA eligible physicians, would be assumed to have an average physician Part B charge per physician per year factor of \$30,000 (\$3,000,000/100). However, we did not pursue this option because the approach results in an average revenue amount across all potentially qualifying MA EPs with respect to a qualifying MA organization and, therefore, would include revenue amounts that exceed the annual per-professional ceiling on incentive payments under FFS for *all* EPs. We believe such a result is contrary to the legal requirement that qualifying MA organizations are to incentive payments only for qualifying MA EPs that actually provide at least 20 hours per week of patient care services. Under this method there would also be no way to know if the EP provided 80 percent of his/her professional Medicare services to enrollees of the organization.

We also considered a reporting system for which qualifying MA organizations would be required to report eligible-professional-specific information along with MA patient encounters for nonhospital-based office visits. Specifically, we examined requiring qualifying MA organizations to report qualifying MA EP encounters with MA plan enrollees based on the five levels of office visit codes recognized by Medicare FFS.

We would use such reports to estimate the amount of compensation that a qualifying MA EP working primarily for a qualifying MA organization would be eligible to receive under Medicare FFS. For example, a qualifying MA EP with a primary care specialty might have an average of 10 MA patient low/moderate intensity office visits with members of a qualifying MA organization per day.

Such an EP would potentially qualify for the maximum Medicare FFS EP incentive payment in the first year based on a calculation of $\$63 * 10 * 52 = \$32,760$ —which is more than the Medicare FFS EHR incentive program threshold of \$24,000 necessary to qualify for the maximum incentive payment of \$18,000 if the first payment year were 2011 or 2012.

We estimated the national average FFS allowed amounts for the 5 levels of office visit codes (CPT codes 99211–99215) in 2009 to be: \$20, \$39, \$63, \$95, \$129, respectively. We contemplated allowing, but not requiring, qualifying MA organizations to report consultation codes for specialist physicians (CPT codes 99241–99245) estimated to have national average FFS allowed amounts of \$50, \$94, \$129, \$190, and \$234, respectively.

However, we now believe that such a process would be administratively burdensome and difficult to operationalize. Therefore, we are proposing an alternative approach, but seek input from interested parties as to which of these approaches, or perhaps others, would best address the statutory requirement to compensate qualifying MA organizations for qualifying MA EPs the amount that would be payable if payment for services furnished by such professionals were made under Part B instead of Part C.

We propose an approach in which the revenue received by the qualifying MA EP for services provided to enrollees of the qualifying MA organization would serve as a proxy for the amount that would have been paid if the services were payable under Part B. Under this approach, the qualifying MA organization would report to us the aggregate annual amount of revenue received by each qualifying MA EP for MA plan enrollees of the MA organization. We would calculate the incentive payment amount due the qualifying MA organization for each qualifying MA EP as an amount equal to 75 percent of the reported annual MA revenue of the qualifying MA EP, up to the maximum amounts specified under section 1848(o)(1)(B) of the Act.

For qualifying MA EPs who are compensated on a salaried basis, we propose requiring the qualifying MA organization to develop a methodology for estimating the portion of the qualifying MA EP's salary attributable to providing services that would otherwise be covered as professional services under Part B of Medicare to MA plan enrollees of the MA organization. The methodology, which would require review and approval by us, could be based on the relative share of patient

care hours spent with MA enrollees of the organization or another reasonable method. So, for instance, if a qualifying MA EP spends 30 percent of his or her time providing covered Part B physician office services to MA plan enrollees, then the qualifying MA organization would report 30 percent of the qualifying MA EP's salary as annual revenue, which would be used to compute the amount of the MA incentive payment due to the qualifying MA organization for the qualifying MA EP. Thus, if the qualifying MA EP had a base salary of \$150,000, 30 percent would be \$45,000—which is well over the threshold of \$24,000 needed by the MA organization to qualify for a maximum incentive payment of up to \$18,000 (70 percent of \$24,000) for such a qualifying MA EP in any year. We also propose to require that salaries be prorated to ensure that the amount reported reflects the salary paid for the applicable year.

Salaried physicians' compensation typically does not include an allowance for administrative practice costs. Given that Part B allowed amounts do include practice expense costs, we propose allowing qualifying MA organizations to identify, where appropriate, an additional amount related to overhead that would be added to the qualifying MA EP's estimated Part B compensation. To the extent Medicare FFS compensation to physicians includes an amount for office space rental, office staffing, and equipment, we believe that qualifying MA organizations should also be permitted to include an amount for overhead related to such costs not directly experienced by salaried qualifying MA EPs. In § 495.204(b)(4)(ii), we propose requiring qualifying MA organizations to develop a methodology for estimating the additional amount related to overhead attributable to providing services that would otherwise be covered under Part B of Medicare. The methodology would require review and approval by us.

For qualifying MA EPs who are not salaried (that is, who are paid on a capitated or fee-for-service basis), we propose in § 495.204(b)(5) to require qualifying MA organizations to obtain attestations from such EPs and to submit to CMS information from the attestations as to the amount of compensation received by the EPs for MA plan enrollees of the MA organization. We are proposing such attestations because many EPs are not paid directly by MA organizations, but rather by intermediary contracting entities, such as physician groups, and as a result the qualifying MA

organization may not otherwise know how much compensation is received by each qualifying MA EP. In reporting compensation, we are proposing that the EPs include only those amounts for professional services that would otherwise be payable under Part B and for which payment would be made under, or would be based on, the Medicare physician fee schedule.

As mentioned previously, in applying the instruction in section 1853(m)(3)(A) of the Act to substitute for the amount specified under section 1886(n)(2) of the Act an amount similar to the estimated amount in the aggregate that would be payable if payment for the hospitals' services were made under Part A instead of Part C, we read the term "aggregate" to mean the aggregate installment payments made by us if EHR incentive payments were made under Part A instead of Part C.

Incentive payments to eligible hospitals under the Medicare FFS EHR incentive program are comprised of three components: (1) An initial amount composed of a base incentive payment of \$2,000,000 and a second incentive payment amount of \$200 per discharge for discharges 1,150–23,000 during a 12-month period selected by the Secretary; (2) the Medicare share; and (3) a transition factor. As discussed in the preamble related to proposed § 495.104(c), for purposes of calculating incentive payments to eligible hospitals under the Medicare FFS EHR incentive program, we are proposing that the 12-month period be based on the FFY. For the purpose of calculating incentive payments for qualifying MA-affiliated eligible hospitals, we similarly are proposing that the 12-month period be based on the FFY.

Section II.B. of this proposed rule discusses our proposed methodology for calculating the incentive payment for qualifying eligible hospitals under the Medicare FFS EHR program. As set forth in proposed § 495.204(c)(2), we propose to use the FFS EHR hospital incentive program for purposes of calculating and making the incentive payment for qualifying MA-affiliated hospitals. To the extent data are not available to reimburse MA-affiliated hospitals through the FFS hospital incentive program, we propose to require submission of such data to us and adopt the same definition of "inpatient-bed-days" and other terms proposed under the Medicare FFS EHR hospital incentive program specified in § 495.104 of this proposed rule. In such a case we propose in § 495.204(c)(1) to make payment for such MA-affiliated eligible hospitals to the qualifying MA organization.

The formula for calculating the hospital incentive payment under the Medicare FFS hospital incentive program is an initial amount of the sum of the base amount of \$2,000,000 per hospital plus an additional \$200 per discharge for discharges 1,150 through 23,000 for that hospital in that payment year. This initial amount is then multiplied by a transition factor and then again by the Medicare share. These last two numbers are fractions and will tend to reduce the initial amount computed in the first step.

Similar to the Medicare FFS EHR hospital incentive program, we propose to use inpatient-bed-day data, discharges, and other components of the FFS calculation for each qualifying MA-affiliated eligible hospital from the hospital-specific fiscal year that ends during the FFY prior to the FFY that serves as the payment year. To the extent such data are not already available to us through the normal submission of hospital cost reporting data, we propose requiring qualifying MA organizations seeking reimbursement for their qualifying MA-affiliated eligible hospitals to submit similar data.

We can only pay for qualifying MA-affiliated eligible hospitals under common corporate governance based on inpatient-bed-days computed on a fiscal year basis where less than one-third of the inpatient-bed-days of Medicare patients are covered under Medicare FFS—Part A. However, it does not appear that reimbursement *only* under the MA EHR incentive program is required for qualifying MA-affiliated eligible hospitals that are under common corporate governance. Rather, section 1853(m)(3)(B), of the Act only prohibits payment under the MA EHR incentive program when Medicare hospital inpatient-bed-days covered under Part A exceed 33 percent of all Medicare inpatient-bed-days. Although eligibility under the MA EHR hospital incentive program is not available to qualifying MA organizations for any specific hospital when FFS inpatient-bed-days exceed 33 percent of the Medicare total, a qualifying MA organization could be reimbursed through the Medicare FFS EHR hospital incentive payment program for qualifying hospitals under common corporate governance even for hospitals with very low ratios of FFS to MA inpatient-bed days.

Given that the hospital incentive payment methodology and payment amount will be identical under the Medicare FFS EHR incentive program and the MA EHR incentive program, and given that there is no statutory

prohibition on reimbursing a qualifying MA-affiliated eligible hospital through the Medicare FFS EHR incentive program, for purposes of administrative efficiency, and pursuant to our authority under section 1857(e) of the Act to add new "appropriate" contract terms (incorporated for Part D by section 1860D–12(b)(3)(D) of the Act), we propose requiring that qualifying MA organizations receive incentive payments for qualifying MA-affiliated eligible hospitals through their affiliated hospitals under the Medicare FFS EHR incentive program if they are eligible for such payments, rather than through the MA EHR incentive program. We believe this is the most efficient way in which to administer the MA EHR hospital incentive program in light of the expected low volume of MA-affiliated eligible hospitals (approximately 50 hospitals), and in light of preliminary data which indicates that MA-affiliated eligible hospitals already submit Medicare cost reporting data to us from which we can compute hospital incentive payments due. To the extent sufficient data do not exist to make such payments under the Medicare FFS EHR incentive program, qualifying MA organizations will be required to submit additional data to us.

Finally, to the extent payments are made to qualifying MA organizations for qualifying MA EPs or qualifying MA-affiliated eligible hospitals, we propose to conduct selected compliance reviews to ensure that EPs and eligible hospitals for which such organizations received incentive payments were actually meaningful users of certified EHR technology, in accordance with our existing authority in section 1857(d) of the Act and 42 CFR 422.504 of the regulations related to protections against fraud. The reviews would include validation of meaningful user attestations, the status of the organization as a qualifying MA organization, and verification of both meaningful use and data used to calculate incentive payments. We propose requiring MA organizations to maintain evidence of compliance with all aspects of the MA EHR incentive payment program for 10 years after the date payment is made with respect to a given payment year. Payments that result from incorrect or fraudulent attestations, cost data, or any other submission required to establish eligibility or to qualify for a payment, will be recouped by CMS from the MA organization.

4. Timeframe for Payment

For payments to qualifying MA EPs, in § 495.206 we propose the time frame

for payment to be after the Medicare FFS program computes incentive payments due under the Medicare FFS EHR incentive program—so the first possible incentive payments would be made sometime in early 2012. We propose that payments for qualifying MA-affiliated eligible hospitals under common corporate governance occur in the same manner and in the same time frame as payments made under the Medicare FFS EHR incentive program to “subsection (d)” hospitals as discussed in section II.B.2.d. of this proposed rule.

We propose to define “payment year” with respect to qualifying MA EPs in § 495.200. Section 1853(l)(3)(C) of the Act directs us to establish the same first payment year for all EPs with respect to any specific qualifying MA organization. Consistent with the statute, we propose to pay a qualifying MA organization on the same schedule for all of its qualifying MA EPs. In other words, the first year during which the qualifying MA organization receives an incentive payment for its qualifying EPs will be considered the first payment year for all of its qualifying EPs. Accordingly, for purposes of determining the applicable incentive payment limits, the second, third, fourth, and fifth years during which the qualifying MA organization receives an incentive payment for its qualifying EPs will be considered the second, third, fourth, and fifth payments years for each of its qualifying EPs, regardless of whether the MA organization claimed an incentive payment for a particular EP for a prior payment year. Such a consistent payment cycle relative to qualifying MA organizations and qualifying MA EPs obviates the need to track payment years and payment adjustment years based on prior payments or adjustments with respect to any individual qualifying MA EP. Rather, for purposes of payment years and payment adjustment years, any EP employed by or partnering with any specific MA organization will be on the same cycle with respect to that organization.

Similar to the Medicare FFS EHR incentive program, payment to qualifying MA organizations for qualifying MA EPs and payment for qualifying MA-affiliated eligible hospitals is available only for a finite number of years. As previously discussed in the section on the calculation of MA incentive payments, above, a qualifying MA organization can receive an incentive payment of up to \$18,000 for each of its qualifying MA EPs for its first payment year if its first payment year is 2011 or 2012, or up to \$15,000, if its first payment year is 2013,

or up to \$12,000, if its first payment year is 2014. Note that, similar to the Medicare FFS EHR incentive program, there would be no incentive payments made with respect to a year after 2016.

We propose to define “payment year” with respect to qualifying MA-affiliated eligible hospitals in § 495.200. For incentive payments for qualifying MA-affiliated eligible hospitals, the first year for which an MA organization may claim payment is FY 2011. Similar to the Medicare FFS EHR hospital incentive program, we propose to use the hospital inpatient-bed-days data from the hospital fiscal year that ends during the FFY prior to the fiscal year that serves as the payment year. For qualifying MA-affiliated eligible hospitals, we propose to compute hospital EHR incentive payments due in the same manner as they are being computed in the Medicare FFS hospital incentive payment program. For qualifying MA-affiliated eligible hospitals for which the first payment year is 2011 through 2013, up to 3 additional years of incentive payments are available. For qualifying MA-affiliated eligible hospitals for which the first payment year is after 2015, no EHR payment incentive can be made for that year or any subsequent year. Finally, for qualifying MA-affiliated eligible hospitals for which the first payment year is 2014 or 2015, only 2 (or 1) more year(s) of hospital incentive payments will be available.

Unlike the fixed schedule for application of limitation on incentive payments for MA EPs discussed previously in this section of the proposed rule in which all employed/partnering MA EPs will be paid on the same schedule (first payment year, second payment year, etc.) with respect to any specific qualifying MA organization, we propose to make payments to MA organizations for MA-affiliated eligible hospitals on a hospital-specific basis. In other words, if a qualifying MA organization has some MA-affiliated eligible hospitals with a first payment year of FY 2011, it may have other MA-affiliated eligible hospitals with a first payment year of FYs 2012 through 2015.

5. Avoiding Duplicate Payment

We propose duplicate payment avoidance provisions in § 495.208. Section 1853(l)(3)(B) of the Act, as added by the HITECH Act, is entitled “Avoiding Duplication of Payments.” Subclause (I) of the Act states that to the extent an MA EP is entitled to the maximum incentive payment under section 1848(o)(1)(A) of the Act, the Medicare FFS EHR incentive payment

program—such incentive payment will only be made under the Medicare FFS EHR incentive program. Therefore, before payments can be made to qualifying MA organizations for MA EPs, we must first determine if a maximum incentive payment under the Medicare FFS program has been previously earned by potential MA EPs. Under the Medicare FFS incentive payment program, incentive payment calculations will not be completed for the first payment year, 2011, until the early part of 2012. Therefore, we would not be able to make payments to qualifying MA organizations for MA EPs until claims submissions counted for Medicare FFS incentive payments for CY 2011 have been closed, and payment calculations for participating EP under the Medicare FFS EHR incentive program have been completed in the early part of CY 2012. We will follow the same practice—first computing Medicare FFS incentive payments for EPs and then computing and paying MA incentive payments, where appropriate—in all subsequent payment years.

Subclause (II) of section 1853(l)(3)(B)(i) of the Act further states that to the extent an MA EP is entitled to less than the maximum incentive payment under the Medicare FFS EHR incentive program, that payment is to be made solely under the MA provision. In other words, we will need to withhold Medicare FFS incentive payments from EPs of less than the maximum to the extent such professionals are also identified as MA EPs under section 1853(l)(2) of the Act. Again, we would need to await the computation of payments due EPs under the Medicare FFS EHR incentive program before we can determine whether the EP is entitled to less than the maximum payment amount under the Medicare FFS EHR program, in which case any incentive payment for the EP will only be made to the qualifying MA organization under the MA EHR program, and not to the EP under the Medicare FFS EHR program.

Section 1853(m)(3)(B) of the Act, states that incentive payments for qualifying MA-affiliated eligible hospitals are to be made under either the Medicare FFS hospital incentive payment program, or under the MA hospital incentive payment program. If more than 33 percent of discharges or bed-days of all Medicare patients for a year are covered under Part A, then payment for that year is to only be made under section 1886(n) of the Act—the Medicare FFS EHR incentive program—and no payment is to be made under the MA hospital incentive payment

program. Otherwise, to the extent less than 33 percent of bed days of all Medicare patients for an incentive payment year are covered under Part A, then payment for that incentive payment year may be made under the MA EHR incentive payment program.

Unlike the process we propose to follow related to qualifying EPs (where we will wait for the Medicare FFS incentive payment program to compute eligible physician incentive payments due under that program before determining the amount due under the MA EHR incentive program), we would not need to rely on Medicare FFS EHR incentive payment program calculations before determining eligibility for MA-affiliated hospital incentive payments. We would reimburse all hospitals, including MA-affiliated eligible hospitals, under the Medicare FFS hospital incentive program. We believe that by doing so, we will prevent duplicate payments being made for the same hospitals by Medicare FFS and the MA incentive payment programs. To the extent that qualifying MA organizations are to receive incentive payments through the MA program rather than through their hospitals under the Medicare FFS EHR incentive program due to a lack of sufficient data to make payments under the FFS program, we would identify and reimburse only appropriate qualifying MA organizations for qualifying MA-affiliated eligible hospitals. Such reimbursement will be in a manner similar to the manner in which the Medicare FFS EHR incentive program will reimburse eligible hospitals due an incentive payment under the Medicare FFS EHR incentive program.

In order to avoid duplicate payments and in accordance with section 1853(m)(3)(B)(ii)(II) of the Act, we will not make MA EHR hospital incentive payments to qualifying MA organizations for MA-affiliated eligible hospitals other than through the Medicare FFS EHR hospital incentive payment program without first ensuring that no such payments under the Medicare FFS EHR hospital incentive payments were made.

We invite industry and public comment on our proposed process to eliminate duplicate payments to EPs and MA-affiliated eligible hospitals under the Medicare FFS and MA incentive payment programs.

6. Meaningful User Attestation

We propose meaningful user attestation requirements in § 495.210. For each MA EP and MA-affiliated hospital for which a qualified MA organization seeks an incentive

payment, the organization must attest, in a form and manner specified by us, that its MA EPs and MA-affiliated eligible hospitals are meaningful EHR users, as required by sections 1853(l)(6) and 1853(m)(1) of the Act. We further propose to adopt the definitions of meaningful user proposed under the Medicare FFS program related to EPs and hospitals in proposed § 495.4. We propose to require qualifying MA organizations to attest each payment year whether each of its MA EPs and MA-affiliated eligible hospitals for which it is seeking an incentive payment was a meaningful EHR user for the EHR reporting period for a payment year. A qualifying MA organization must make this attestation for each payment year for which it is seeking an incentive payment for MA EPs and MA-affiliated eligible hospitals. We believe attestations should occur toward the end of a year with respect to that year, since qualifying MA organizations will need to attest to, based on our proposed rule, meaningful use for the appropriate duration and during the appropriate period related to MA EPs and MA-affiliated eligible hospitals before claiming incentive payments for them.

Note that unlike the Medicare FFS EHR incentive program, where we will require the reporting of clinical quality measures—see § 495.8—we will not require qualifying MA organizations to submit clinical quality measures per section 1848(o)(2)(B) of the Act, with respect to EPs, and section 1886(n)(3)(B) of the Act, with respect to eligible hospitals. Consistent with sections 1848(o)(2)(B)(iii) and 1886(n)(3)(B)(iii) of the Act, we note that qualifying MA organizations sponsoring coordinated care MA plans are already required to submit Healthcare Effectiveness Data and Information Set (HEDIS), Health Outcomes Survey (HOS), and Consumer Assessment of Healthcare Providers and Systems (CAHPS) measures per § 422.152 and § 422.516. Coordinated care MA plans include HMO, PPO and RPPO (Regional PPO) plans. Beginning with CY 2010, PFFS and MSA plans will also be required to begin collecting and submitting administrative HEDIS measures.

We believe that all qualifying MA organizations will be organizations offering MA coordinated care plans, and therefore; those MA organizations from which we routinely receive complete HEDIS dataset reporting. Pursuant to sections 1848(o)(2)(B)(iii) and 1886(n)(3)(B)(iii) of the Act, for clinical quality measures which overlap between the existing MA quality reporting program and under the HITECH program, we propose to allow

qualifying MA organizations to continue reporting under the existing MA quality reporting program. For those HITECH clinical quality measures that do not overlap and that are appropriate for the MA program, we are considering requiring that qualifying MA organizations that receive an incentive payment report those measures to CMS. This would ensure that clinical quality measure reporting under HITECH is consistent between the FFS program and MA. An alternative approach would be to require that qualifying MA organizations that receive an incentive payment report all of the HITECH clinical quality measures under section II.A.2 of this proposed rule that are appropriate for the MA program directly to CMS, while also reporting those HEDIS, HOS, and CAHPS measures under the existing MA quality program. This may result in duplicative reporting under the HITECH program and current MA quality reporting, but may provide us with more direct access to quality data under the HITECH program. We invite public comment on these approaches, including alternative methods to consistently treat MA-affiliated providers and FFS providers under the HITECH Medicare incentive program.

Therefore, we propose requiring qualifying MA organizations to submit attestations to us related to meaningful use by MA-affiliated hospitals within 30 days of the close of the FFY—which is the payment year for MA-affiliated hospitals—by October 30. We also propose requiring qualifying MA organization to submit attestations to us related to meaningful use by MA EPs within 30 days of the close of the MA EP payment year—which is a CY—by January 30.

7. Posting Information on the CMS Web Site

Sections 1853(l)(7) and 1853(m)(5) of the Act, require us to post information on an Internet Web site related to the receipt of incentive payments under the MA EHR incentive program. Information would include the names, business addresses, and business phone numbers of each qualifying MA organization receiving an incentive payment under this section for qualifying MA EPs and hospitals. A list of the names of each qualifying MA EP and qualifying MA-affiliated eligible hospital for which an incentive payment has been made would also be posted. Since this requirement is applicable to other Medicare EPs and eligible hospitals, we have included this requirement in proposed § 495.108.

8. Limitation on Review

Section 1853(l)(8) of the Act states that there shall be no administrative or judicial review under section 1869 of the Act, section 1878 of the Act, or otherwise of the methodology and standards for determining payment amounts and payment adjustments under the MA EHR EP incentive program. This includes provisions related to duplication of payment avoidance and rules developed related to the fixed schedule for application of limitation on incentive payments for all qualifying MA EPs related to a specific qualifying MA organization. This also includes the methodology and standards developed for determining qualifying MA EPs and the methodology and standards for determining a meaningful EHR user, including the means of demonstrating meaningful use and the selection of measures. We propose to codify these requirements in § 495.212(b).

Section 1853(m)(6) of the Act, as added by the HITECH Act, states that there shall be no administrative or judicial review under section 1869, section 1878, or otherwise of the methodology and standards for determining payment amounts and payment adjustments under the MA EHR hospital incentive program. This includes provisions related to duplication of payment. This also includes the methodology and standards developed for determining qualifying MA hospitals and the methodology and standards for determining a meaningful EHR user, including the means of demonstrating meaningful use and the selection of measures. We propose to codify these requirements in § 495.212(c).

9. Conforming Changes

Sections 4101(e) and 4201(d)(2) and (3) of the HITECH Act provide conforming amendments to Part C of the Social Security Act. Therefore, we are proposing the following conforming changes to the regulations text:

- Revising § 422.304 by adding a new paragraph (f) to account for the amendment to section 1853(a)(1)(A) of the Act referencing the additional EHR incentive payments that may be made to qualifying MA organizations in the section of the statute that provides for monthly capitation payments to MA organizations. (This addition would also act as a cross-reference to MA EHR incentive payment rules in proposed subpart C of part 495 of this chapter.)
- Revising § 422.306(b)(2) by adding a new paragraph (iv) to address the amendments to section 1853(c)(1)(D)(i)

of the Act which exclude the EHR incentive payments made to EPs and hospitals under the Medicare FFS program from the computation of FFS costs in a year for the purpose of computing MA monthly capitation amounts.

- Revising § 422.308 by adding a new paragraph (a)(1) to address the amendments to section 1853(c)(1)(D)(1) and (c)(6)(A) of the Act regarding the exclusion of FFS Medicare EHR incentive payments and adjustments from the calculation of the national per capita growth percentage.

- Revising § 422.322 by adding a new paragraph (a)(3) to account for the amendments to section 1853(c)(6)(A) and (f) of the Act specifying that the source of EHR incentive payments to qualifying MA organizations are from the Federal Hospital Insurance Trust Fund or the Supplementary Medical Insurance Trust Fund.

- Revising § 422.322(b) by adding a reference to § 495.204 to address the amendment to section 1851(i)(1) of the Act that indicates that EHR incentive payments are instead of incentive payments that would otherwise be payable under original Medicare.

10. Payment Adjustment and Future Rulemaking

In future rulemaking we will develop standards related to payment adjustments to qualifying MA organizations related to MA EPs and MA-affiliated eligible hospitals that are not meaningful users of certified EHR technology. We solicit comment on how we can most effectively and efficiently apply payment adjustments to qualifying MA organizations whose MA eligible EPs and hospitals have not successfully meaningfully used certified EHR technology.

The statutory requirement related to imposition of payment adjustments with respect to MA EPs is set forth in section 1853(l) of the Act. Specifically, section 1853(l)(4) of the Act requires that instead of applying the payment adjustment in section 1848(a)(7) of the Act, we apply the payment adjustment to the Medicare physician expenditure proportion. This is our estimate of the proportion of the expenditures under Parts A and B paid to the qualifying MA organization in the form of capitation payments under section 1853 of the Act that are not attributable to the EHR incentive payment program, that are attributable to expenditures for physician services. In the case of a qualifying MA organization that attests that not all MA EPs of the organization are meaningful EHR users with respect to years beginning with 2015, we are

directed to apply the payment adjustment on the proportion of the capitation payment with respect to all such EPs of the organization that are not meaningful users for such year. The adjustment amount is 1 percent for 2015, 2 percent in 2016, and 3 percent in 2017 and subsequent years.

The statutory requirement related to imposition of payment adjustments with respect to MA-affiliated eligible hospitals is provided in section 1853(m) of the Act. Specifically, section 1853(m)(4) of the Act requires us to apply the adjustment to the hospital expenditure proportion, which is our estimate of the proportion of the expenditures under Parts A and B paid to the qualifying MA organization in the form of capitation payments under section 1853 of the Act that are not attributable to the EHR incentive payment program, that are attributable to expenditures for inpatient hospital services. In the case of a qualifying MA organization that attests that not all MA-affiliated eligible hospitals of the organization are meaningful EHR users with respect to years beginning with 2015, we are directed to apply the payment adjustment on the proportion of all such MA-affiliated eligible hospitals of the organization that are not meaningful users for such year. The adjustment amount is of three-fourths of the market basket increase related to a hospital by a 33⅓ percent reduction in 2015, by a 66⅔ percent reduction in 2016, and by a 100 percent reduction in 2017 and all subsequent years. Effectively, the reduction is of all but 25 percent of the market basket increase for a specific hospital in years after 2016.

We welcome comments on these incentive payment adjustments and on how we can most effectively and efficiently apply payment adjustments to qualifying MA organizations whose EPs and MA-affiliated hospitals have not successfully meaningfully used certified EHR technology. Any comments received will be considered in developing future rulemaking.

D. Medicaid Incentives

1. Overview of Health Information Technology in Medicaid

Under the HITECH Act, State Medicaid programs, at their option, may receive Federal financial participation (FFP) for expenditures for incentive payments to certain Medicaid providers to adopt, implement, upgrade, and meaningfully use certified EHR technology. Additionally, FFP is available to States for administrative expenses related to administration of those incentive payments as long as the

State meets certain conditions. Section 1903(a)(3)(F)(i) of the Act, as amended by section 4201 of the HITECH Act, establishes 100 percent FFP to States for providing incentive payments to eligible Medicaid providers (described in section 1903(t)(2) of the Act) to adopt, implement, upgrade, and meaningfully use certified EHR technology. The incentive payments are not direct reimbursement for the purchase and acquisition of such technology, but rather are intended to serve as incentives for EPs and eligible hospitals to adopt and meaningfully use certified EHR technology.

Section 1903(a)(3)(F)(ii) of the Act, as amended by section 4201 of the HITECH Act, also establishes 90 percent FFP to States for administrative expenses related to carrying out the substantive requirements associated with the incentive payments. As discussed later in this proposed rule, we interpret these administrative expenses as including approvable expenses related to oversight activities and promotion of health information exchange.

It is important to note that we do not believe that the Medicaid incentive and administrative payments authorized under section 4201 of the HITECH Act should be viewed in isolation. Rather, we encourage States, providers, and other stakeholders to view these new programs in concert with the numerous other initiatives recently undertaken and currently being promoted by both CMS and the Department to encourage advancements in health care technology and health information exchange. These initiatives include the following:

- The establishment of the Office of the National Coordinator (first through executive order in 2004 and then as legislatively mandated in the HITECH Act);
- The Medicaid Transformation Grant program authorized by section 6081 of the Deficit Reduction Act of 2005 (Pub. L. 109–171). This program provided \$150 million in grants in FY 2007 through FY 2008 to States to support innovative methods for transforming Medicaid programs. Twenty-two States focused on HIT, with initiatives ranging from the use of statewide EHRs for beneficiaries, to mechanized clinical decision support, to e-prescribing, to electronic health information exchange. For more information on the program, we refer readers to: <http://www.cms.hhs.gov/MedicaidTransGrants>.

- The Medicaid Information Technology Architecture (MITA) initiative and framework. MITA is a plan to promote improvements in the Medicaid enterprise and the systems

that support it through collaboration between CMS and the States. The MITA framework consists of models, guidelines, and principles for States to use as they plan and implement business and technology enterprise solutions. Integral to the MITA is the State's Medicaid Management Information System (MMIS). The MMIS contains a great deal of claims data and other Medicaid programmatic information that we believe should be used by States in analyzing their current HIT environments. Once States establish a baseline assessment, they can then plan the steps necessary to transition towards achieving some of the objectives of the HITECH Act, such as improving both quality of care and health care outcomes. In addition, the MITA framework is CMS's initiative that will allow States to modernize and transform their MMIS to improve the administration of the Medicaid program, while supporting the States' need for flexibility, adaptability, and rapid response to changes in the unique aspects of their individual Medicaid programs. The ultimate goal of MITA is to develop seamless and integrated systems that communicate effectively and that are interoperable, both within and across States as well as with other health care entities and payers, such as public health departments and non-Medicaid payers. For more information on MITA, we refer readers to: <http://www.cms.hhs.gov/MedicaidInfoTechArch/>.

We believe that the HITECH Act incentives create a unique opportunity for States and Medicaid providers to build upon prior and current efforts in HIT in order to help achieve interoperable health information exchange in health care. We believe that States should build upon the lessons learned from these initiatives in order to ensure that the incentive and administrative payments are leveraged in a way that maximizes the role of HIT in enhancing quality and access, reducing costs, and improving health care outcomes.

We also plan to ensure public involvement as the HIT environment evolves, both as a result of the HITECH Act incentives, as well as a result of other Departmental HIT initiatives. We have already convened several State calls on the HITECH Act, including discussing the definition of meaningful use of certified EHR technology, and the impact the definition would have on specific provider groups. More information on the content of these calls can be found in section II.A.2.a of this proposed rule. We convened additional calls with State staffs on the Medicaid

EHR incentives leading up to our development of this proposed rule. Issues addressed include policies such as State oversight of adopting, implementing, and upgrading certified EHR technology; alternative fiscal agents under consideration; and validating data to establish program eligibility.

We also released a State Medicaid Director's letter on September 1, 2009. This letter outlines steps State Medicaid agencies can take to assess the current status of their HIT efforts; develop a roadmap for achieving their HIT objectives in support of the Medicaid EHR incentive program; set Medicaid-specific performance goals and incentives for provider adoption of HIT; and partner with a broad range of stakeholders. Furthermore, we conducted a follow-up technical assistance call with State Medicaid Directors and their staffs to provide an overview and answer questions.

Finally, as required by section 1903(t)(10) of the Act, we will be reporting to Congress on the status, progress, and oversight of the overall EHR incentive program. These reports will discuss steps taken to avoid duplicate Medicare and Medicaid incentive payments to EPs, the extent to which Medicaid EPs and hospitals have adopted certified EHR technology as a result of the incentive payments, and any improvements in health outcomes, clinical quality, or efficiency resulting from the adoption of such technology.

• 2. General Medicaid Provisions

In the proposed § 495.342 and § 495.344 we provide the general rule that States, at their option, may receive: (1) 90 percent FFP for State expenditures related to the administration of an EHR incentive program for certain Medicaid providers that are adopting, implementing, or upgrading and meaningfully using certified EHR technology; and (2) 100 percent FFP for State expenditures for those incentive payments.

• 3. Identification of Qualifying Medicaid EPs and Eligible Hospitals

a. Overview

As specified in section 1903(t)(2) of the Act, only certain Medicaid providers will be eligible for incentive payments. This section of the preamble discusses some of these eligibility requirements, including requirements relating to patient volume, whether a provider is hospital-based, and whether an EP is practicing predominantly in a federally-qualified health center (FQHC) or a rural health clinic (RHC). Proposed

regulations relating to these requirements may be found at § 495.304 through § 495.306.

• b. Program Participation

As specified under section 1903(t)(2)(A) of the Act, Medicaid participating providers who wish to receive a Medicaid incentive payment must meet the definition of a “Medicaid EP.” This definition (1903(t)(3)(B) of the Act) lists five types of Medicaid professionals: Physicians, dentists, certified nurse-midwives, nurse practitioners, and physician assistants practicing in an FQHC or RHC that is so led by a physician assistant.

Additionally, to qualify for incentives, most Medicaid EPs cannot be “hospital-based.” We propose to use the same definition of “hospital-based” as used in the Medicare EHR incentive program, as sections 1848(o)(1)(C) and 1903(t)(3)(D) of the Act use almost identical definitions of the term. We refer readers to section II.A. of this preamble for a proposed definition of “hospital-based,” and for a thorough discussion of our proposed methodology.

The only exception to this rule is that Medicaid EPs practicing predominantly in an FQHC or RHC are not subject to the hospital-based exclusion.

Medicaid EPs must also meet the other criteria for Medicaid incentive payment eligibility, such as the patient volume thresholds or practicing predominantly in an FQHC or RHC, as described in this subpart. Since the statute at 1903(t)(2)(iii) of the Act does not define “practices predominantly,” we propose that an eligible professional practices predominantly at an FQHC or an RHC when the clinical location for over 50 percent of his or her total patient encounters over a period of 6 months occurs at an FQHC or RHC.

Acute care and children’s hospitals are listed in section 1903(t)(2) of the Act as the only two types of institutional providers potentially eligible for Medicaid incentive payments. These terms are specific to the Medicaid EHR incentive program and are not currently defined in the Medicaid regulations. Consequently, we propose to define these terms in § 495.302.

As specified under section 1903(t)(2)(B) of the Act, to qualify for incentive payments acute care hospitals also must meet patient volume threshold requirements, as specified in proposed § 495.306. Children’s hospitals do not have patient volume requirements for Medicaid incentive program participation.

(1) Acute Care Hospitals

“Acute care” is defined as the necessary treatment of a disease or injury for only a short period of time in which a patient is treated for a brief but severe episode of illness.¹ Many hospitals can be considered acute care facilities if they provide both inpatient and outpatient services with the goal of discharging the patient as soon as the patient is deemed stable, with appropriate discharge instructions. We are proposing that for purposes of Medicaid incentive payments, an “acute care hospital” is defined as: A health care facility where the average length of patient stay is 25 days or fewer. For purposes of participation in the Medicaid EHR incentive program, this proposed definition ensures that hospitals are designated as acute care hospitals based on the level and nature of care they provide. This definition also includes some specialty hospitals where the average length of stay is 25 days or fewer. This definition of acute care hospitals will exclude specialty providers and long-term care facilities where the average patients’ length of stay exceeds 25 days. To further refine the definition, we reviewed the Medicare-issued CCN. CCNs are issued to categories of providers who meet Federal requirements (known as conditions of participation) to participate in the Medicare program. State Medicaid agencies look to Medicare’s conditions of participation when deciding whether to issue provider agreements to many categories of providers. In the case of inpatient hospital services § 440.10(a)(3)(iii) requires that for inpatient hospital services provided to Medicaid beneficiaries to be eligible for FFP, those services must be provided in an institution that meets the requirements for participation in Medicare as a hospital, and such hospitals receive CCNs.

Hospital CCNs are structured such that the first two digits represent the State in which the hospital is located, and the next four digits identify the type of facility and are assigned sequentially from the appropriate block of numbers. Short-stay general hospitals receive CCNs whose number range is 0001 through 0879. The 11 cancer hospitals in the United States also are issued CCNs within that number range. To allow some flexibility for hospital participation in the Medicaid EHR incentive program, we are proposing to define acute care hospitals for purposes

of this Medicaid EHR incentive program as those with an average patient length of stay of 25 days or fewer and with a CCN that has the last four digits in the series 0001 through 0879 (that is, short-term general hospitals and the 11 cancer hospitals in the United States).

We also recognize a category of long-term care hospitals, which we are planning to exclude from the definition. Long term acute care hospitals are defined for Medicare purposes in regulations at 42 CFR 412.23(e). Specifically § 412.23(e)(2)(i) states that the hospital must have an average Medicare inpatient length of stay of greater than 25 days (which includes all covered and non-covered days of stay of Medicare patients).

We considered allowing both short-term and long-term acute care hospitals to meet the definition of acute care hospital for purposes of the Medicaid incentive payments. However, we are not proposing a definition that encompasses both types of acute care hospitals because CMS’ interpretation was that long-term acute care hospitals did not satisfy the intent of the statute, which we believe intends to include general acute care hospitals. In addition, CMS knew of at least one State that does not recognize long-term acute care hospitals as a Medicaid provider type. We therefore drew the line at 25 days, the cut-off between short-term general and specialty hospitals and long-term acute care hospitals. We used this cut-off in conjunction with the list of CMS CCNs (which also distinguish between short-term and long-term hospitals (see CMS State Operations Manual Section 2779A1, as revised on April 20, 2007 and effective on October 1, 2007) in order to be as inclusive as possible within statute. Since Congress specifically singled out children’s hospitals in addition to acute care hospitals, we believe that if Congress intended to include long-term care hospitals, it would have similarly given them separate mention. In addition, Congress specifically did not include nursing facilities, another category of long-term care provider (and an important source of Medicaid care) as a provider type eligible for incentive payments. CMS read this as further evidence that the statute did not intend inclusion of long-term care facilities.

(2) Children’s Hospitals

The statute also does not include a definition for “children’s hospitals.” To assist with the development of a definition of “children’s hospitals” for purposes of the Medicaid EHR incentive program, we convened teleconferences with States to gather input on topics

¹ State of Connecticut, Office of Health Care Access, “The Health of Connecticut’s Hospitals,” report released January 16, 2001, page 17.

that should be defined in this proposed rule. Participants noted that one critical issue is whether a children's wing of a general hospital could be considered a children's hospital for purposes of qualifying for a Medicaid incentive payment.

As with the acute care hospital definition, we again looked to Medicare-issued CCNs and recognized that numbers whose last four digits are in the 3300 to 3399 series are assigned to children's hospitals. Currently in the United States there are 78 certified children's hospitals, including both freestanding and hospital-within-hospital facilities.

For purposes of the Medicaid EHR incentive program, we propose one definition to include only separately certified children's hospitals, with CCNs in the 3300–3399 series in the definition of eligible “children's hospital.” By proposing to define “children's hospital” in this way, CMS would (1) prevent general acute care hospitals, which cannot themselves qualify for the incentive because they do not meet the 10 percent Medicaid patient volume, from using the fact that they have a pediatric wing as justification for requesting a Medicaid incentive payment; (2) exclude many of the facilities that are perceived by the public as children's hospitals, but do not meet the Medicare standards as either freestanding or hospital-within-hospital children's hospitals; and (3) exclude some pediatric specialty hospitals which have CCNs as psychiatric or rehabilitation hospitals.

An alternative proposed definition of a “children's hospital” would include those hospitals with Medicare provider numbers in the following series:

- 0001 through 0879—Short-term (General and Specialty) Hospitals.
- 3025 through 3099—Rehabilitation Hospitals (Excluded from Prospective Payment Systems).
- 3300 through 3399—Children's Hospitals (Excluded from Prospective Payment Systems).
- 4000 through 4499—Psychiatric Hospitals (Excluded from Prospective Payment Systems).

This definition, for the purposes of the Medicaid HIT Incentive payments, would apply only to those freestanding hospitals within the above mentioned series that exclusively furnish services to individuals under age 21.

This broader definition would (1) still prevent acute care hospitals that cannot independently qualify for the incentive because they do not meet the 10 percent Medicaid patient volume from using the fact that they have a pediatric wing as justification for requesting an HIT

incentive payment; (2) allow for participation in the incentive program by the greatest number of children's hospitals, including rehabilitative and psychiatric specialty hospitals; and (3) align with Federal efforts aimed at improving healthcare quality for all children, including those with physical and mental diseases/disabilities.

We are soliciting comment on the proposed definitions of “children's hospital” as it applies to the Medicaid EHR incentive program recognizing that there may be additional alternative definitions that could have a positive impact on the health care received by children.

c. Medicaid Professionals Program Eligibility

For Medicaid EPs, the general rule (subject to the two exceptions listed below) is that the EP must have at least 30 percent patient volume attributable to those who are receiving Medicaid. Section 1903(t)(2)(A)(i) of the Act provides authority to the Secretary to establish the methodology by which such patient volume will be estimated. We propose that to establish such patient volume, the EP must have a minimum of 30 percent of all patient encounters attributable to Medicaid over any continuous 90-day period within the most recent calendar year prior to reporting. There are two exceptions to the general 30 percent rule discussed previously. The first exception is that a pediatrician may have at least 20 percent patient volume attributable to those who are receiving health care services under the Medicaid program, as estimated in accordance with a methodology established by the Secretary (section 1903(t)(2)(A)(ii) of the Act). Again, the method we propose to use is that the pediatrician must have a minimum 20 percent of all patient encounters attributable to Medicaid over any continuous 90-day period within the most recent calendar year prior to reporting.

The second exception is that Medicaid EPs practicing predominantly in an FQHC or RHC must have a minimum of 30 percent patient volume attributable to “needy individuals.” Again, the method we propose to use is that 30 percent of all patient encounters be attributable to needy individuals over any continuous 90-day period within the most recent calendar year prior to reporting.

Section 1903(t)(3)(F) of the Act defines needy individuals as individuals meeting any of the following three criteria: (1) They are receiving medical assistance from Medicaid or the Children's Health

Insurance Program (CHIP); (2) they are furnished uncompensated care by the provider; or (3) they are furnished services at either no cost or reduced cost based on a sliding scale determined by the individual's ability to pay. An explanation of how we propose to apply each of these criteria is described in detail in this section of the proposed rule.

We propose this flexible patient volume methodology in order to capture the highest number of true Medicaid practitioners potentially eligible for the EHR incentive program. We believe Congress set the high patient volume thresholds in order to offer these incentives to the practitioners whose practices are open and accessible to Medicaid beneficiaries. We noted that many Medicaid eligible individuals, such as children, may seek care at specified times of the year, such as the beginning of the school-year for required immunizations. Since there are five different types of providers, varying from specialty to primary care, we thought the flexibility would capture any seasonal encounter adjustments in the year, while still honoring Congress' intent to reward higher-volume Medicaid practitioners.

d. Calculating Patient Volume Requirements

As required by section 1903(t)(2) of the Act and discussed in the previous section, all EPs and the vast majority of hospitals will need to meet certain patient volume thresholds in order to be eligible for incentive payments. (The only exception to this rule is for children's hospitals, which have no patient volume threshold requirement).

In addition, where patient volume is a criterion, most providers will be evaluated according to their “Medicaid” patient volume, while some professionals (those practicing predominantly in an FQHC or RHC) will be evaluated according to their “needy individual” patient volume.

We propose to define “patient volume” in § 495.302 to be a minimum participation threshold for each individual Medicaid provider (with the exception of children's hospitals).

For the Medicaid patient volume, this threshold (represented below) is calculated using as the numerator the individual hospital's or EP's total number of Medicaid patient encounters in any representative continuous 90-day period in the preceding calendar year and the denominator is all patient encounters for the same individual professional or hospital over the same 90-day period. We are not prescribing standards for what is a “representative”

period, but we intend to apply a plain meaning test. In other words, if a reasonable person would not consider the selected period to be representative (for example, because the selected period included a short-term temporary Medicaid outreach program), then it would not support a threshold calculation.

[Total (Medicaid) patient encounters in any 90-day period in the preceding

calendar year/Total patient encounters in that same 90-day period] * 100

For the needy individual patient volume, the threshold (represented below) is calculated in the same manner, but with the numerator equal to the EP's total number of needy individual patient encounters in any representative 90-day period in the preceding calendar year.

[Total (Needy Individuals) patient encounters in any continuous 90-day

period in the preceding calendar year/Total patient encounters in that same 90-day period] * 100

Medicaid EPs and eligible hospitals would be required to annually re-attest to patient volume thresholds to continue to qualify for Medicaid incentive payments. Table 26 demonstrates the above-referenced patient volume thresholds per provider type.

TABLE 26—QUALIFYING PATIENT VOLUME THRESHOLD FOR MEDICAID EHR INCENTIVE PROGRAM

Entity	Minimum 90-day Medicaid patient volume threshold (percent)	
Physicians	30	Or the Medicaid EP practices predominantly in an FQHC or RHC—30% “needy individual” patient volume threshold.
Pediatricians	20	
Dentists	30	
Certified nurse midwives	30	
Physician Assistants when practicing at an FQHC/RHC led by a physician assistant.	30	
Nurse Practitioner	30	
Acute care hospital	10	
Children's hospital	

If a State has an alternative approach to the established timeframe for measuring patient volume, it may propose it to us for review through the State Medicaid HIT Plan (SMHP) (discussed later) and we would make a determination of whether it is an acceptable alternative. To be considered for approval, the alternative approach would require a verifiable data source and justification. In defining the way in which patient volume is established, we provide for a consistent methodology per the statute, but also allow for the possibility that States may propose acceptable alternatives that synchronize with existing data sources, which could decrease State data burdens. This alternative approach must provide an auditable record (that is, a record of how the professional demonstrated patient volume) for CMS to monitor the States' oversight of the Medicaid EHR incentive program implementation.

In determining the “needy individual” patient volume threshold that applies to EPs practicing predominantly in FQHCs or RHCs, section 1902(t)(2) of the Act authorizes the Secretary to make a downward adjustment to the uncompensated care figure to eliminate bad debt data. We interpret bad debt to be consistent with the Medicare definition, as specified at § 413.89(b)(1). Under Medicare, bad debts are amounts considered to be uncollectible from accounts and notes receivable that were created or acquired in providing

services. “Accounts receivable” and “notes receivable” are designations for claims arising from the furnishing of services, and are collectible in money in the relatively near future. Providers should be required to use cost reports (for FQHCs and clinics this would be the Medicare 222–92 cost report, or the most recent version of the 222), or other auditable records to identify bad debts. All information under attestation is subject to audit. Our proposed regulations on calculating the needy individual patient volume can be found at § 495.302 and § 495.306.

Further, in establishing the Medicaid patient volume thresholds for EPs and acute care hospitals, section 1902(t)(2) of the Act requires that individuals enrolled in Medicaid managed care organizations (MCOs), prepaid inpatient health plans (PIHPs), or prepaid ambulatory health plans (PAHPs), under 42 CFR Part 438 be included in the calculation. Therefore, in determining patient volume, providers and States should be aware that individuals enrolled in such plans will be included in the patient volume calculation. Acute care hospitals have to meet the 10 percent Medicaid volume threshold.

We also note that although § 438.60 of our regulations would generally prohibit a State from making a direct payment to a provider for services that are included under a contract with an MCO, PIHP, or PAHP, providers contracted with these managed care plans will nevertheless be

eligible for Medicaid EHR incentive payments because those payments are not for services that are included in such a contract. The fact that Congress directed that individuals enrolled in managed care be included in the patient volume calculation demonstrates an intent to allow qualified providers to receive incentive payments, whether they provided their services through capitated care arrangements or fee-for-service. Over 70 percent of Medicaid beneficiaries receive care in a managed care delivery system, and we do not believe that the intent of Congress in creating the incentives program was to remove the providers treating these individuals from the incentives program.

e. Entities Promoting the Adoption of Certified EHR Technology

We are proposing to define “promoting the adoption of certified EHR technology” in § 495.302. Under section 1903(t)(6)(A)(i), incentive payments must generally be made directly to the EP. Section 1903(t)(6)(A)(ii) of the Act provides an exception to permit payment of incentive payments to “entities promoting the adoption of certified EHR technology,” as designated by the State, if participation in the payment arrangement is voluntary for the EP involved. Additionally, the entity must not retain more than 5 percent of the payment for costs unrelated to certified

EHR technology (and support services including maintenance and training) that is for, or is necessary for, the operation of the technology. While the Act authorizes States to designate these entities, the Secretary nevertheless retains authority to define what it means to be “promoting the adoption of certified EHR technology,” as specified in section 1903(t)(6)(A)(ii) of the Act. Section 1102 of the Act authorizes the Secretary to “make and publish such rules and regulations, not inconsistent with this Act, as may be necessary to the efficient administration of the functions with which he or she is charged under this Act.” Since one of our functions is to approve Title XIX plans under sections 1902(b) and 1116 of the Act, and States would need to submit plans as to how they would spend section 4201 of the HITECH Act funds, we have the authority to determine whether a State’s plan for allowing EPs to assign their Medicaid incentive payments to these entities is in compliance with our interpretation of the Act.

We propose to define “promoting” certified EHR adoption to mean the enabling and oversight of the business, operational and legal issues involved in the adoption and implementation of EHR and/or exchange and use of electronic health information between participating providers, in a secure manner, including maintaining the physical and organizational relationship integral to the adoption of certified EHR technology by EPs. For example, health information exchanges have the potential to transform the healthcare system by facilitating timely, accurate, and portable health information on each patient at the point of service. Health Information Exchanges (HIEs), are one type of entity that we believe would meet the definition of an entity that is promoting the adoption of certified EHR technology. HIEs provide the capability to move clinical information electronically between disparate health care information systems while maintaining the meaning of the information being exchanged. HIEs also provide the infrastructure for secondary use of clinical data for purposes such as public health, clinical, biomedical, and consumer health informatics research as well as institution and provider quality assessment and improvement, where permissible under HIPAA and other requirements included in the HITECH Act. In addition, use of health information exchange models can reduce the need for costly point-to-point interfaces between different EHR tools, as used in laboratories and pharmacies, thus providing a more scalable model of

interoperable health information exchange. HIEs promote adoption of certified EHR technology by providing the infrastructure for providers’ EHRs to reach outside of their clinical practice sites and connect with other points of care. Providers report that having a more complete picture of their patients’ healthcare data from other providers and care settings is one of the primary appeals to using EHRs. Without health information exchange, electronic health records are simply digitized filing cabinets and will not achieve their quality of care or cost containment potential. Furthermore, given the proposed definition of meaningful use, HIEs can significantly help Medicaid providers adopt and use EHR in such a way that the goals of the incentive program are met. The inclusion in HITECH of HIE grants to be awarded to States or State-designated Entities by ONC are an additional indication of the symbiotic relationship between health information exchanges and optimal use of EHRs.

Under 1903(t)(6)(A)(ii) of the Act and as proposed in § 495.354, States must establish verification procedures that enable Medicaid EPs to voluntarily assign payments to entities promoting EHR technology. States must guarantee that the assignment is voluntary and that the entity does not retain more than 5 percent of those assigned Medicaid incentive payments for costs unrelated to certified EHR technology. We propose requiring States to publish and make available to all Medicaid EPs the procedures they developed for assigning incentive payments to the third party entities before payments can be assigned. Such publication must also include information about the State’s verification mechanism. The State’s method must assure compliance with the requirement that no more than 5 percent of the Medicaid EP’s annual incentive payment is retained by the entity for costs not related to certified EHR technology.

Although section 1903(t)(6)(A)(ii) of the Act allows assignment of payment to entities promoting the adoption of EHR technology, we wish to clarify that such assignment would not remove the responsibility of the Medicaid EP to individually demonstrate meaningful use of the EHR technology (as discussed in greater detail below). Therefore, entities promoting the adoption would not receive the assigned payments unless the Medicaid EP meets all eligibility criteria. Our proposed definition for promoting the adoption of certified EHR technology is in § 495.302.

4. Computation of Amount Payable to Qualifying Medicaid EPs and Eligible Hospitals

The statute, at sections 1903(t)(1), (t)(4), and (t)(5) of the Act, creates different payment formulas for Medicaid EPs versus hospitals. The payment methodology for Medicaid hospitals shares many aspects of the methodology used for Medicare hospitals.

a. Payment Methodology for EPs

(1) General Overview

Pursuant to section 1903(t)(1)(A) of the Act, payment for EPs equals 85 percent of “net average allowable costs.” While the Secretary is directed to determine “average allowable costs” based upon studies of the average costs of both purchasing and using EHR technology, the net average allowable costs that set payment are capped by statute. As discussed in more detail further on, generally stated, these caps equal \$25,000 in the first year, and \$10,000 for each of 5 subsequent years (there is an exception for pediatricians with under 30 percent Medicaid patient volume, whose caps are two-thirds of these amounts). Thus, the maximum incentive payment an EP could receive from Medicaid equals 85 percent of \$75,000, or \$63,750, over a period of 6 years. EPs must begin receiving incentive payments no later than CY 2016.

(2) Average Allowable Costs

Section 1903(t)(4)(C) of the Act gives the Secretary the authority to determine average allowable costs. Specifically, the Secretary is directed to study the average costs associated with the purchase, initial implementation, and upgrade of certified EHR technology, including support services, and integral related training. The Secretary also is directed to study the average costs of operating, maintaining, and using certified EHR technology. The statute permits the Secretary to use studies submitted by the States.

We conducted a literature review of recent studies on EHR technology to determine the average allowable cost of implementing and using such technology. We reviewed the results from four recent, comprehensive studies. Specifically, HHS’ Office of the Assistant Secretary for Planning and Evaluation commissioned a study by Moshman Associates, Inc., Booz Allen Hamilton, in September 2006—Assessing the Economics of EMR Adoption and Successful Implementation in Physical Small Practice Settings. In this study, EHRs

consisted of a core group of functions that, in various permutations, are often associated with an electronic medical record and frequently include the capacity to: Capture and display clinical notes, display laboratory results, display diagnostic imaging results or reports, order drugs or diagnostic tests, and generate reports.²

The study found that EHR adoption is influenced by a variety of factors, including hardware costs, software costs, the costs of implementation and training, and costs associated with productivity that occur in the early stages of implementation. While there are challenges in making cost comparisons across different studies and across different functionalities (that is, EMRs versus EHRs), the costs per physician ranged between \$33,000 and \$50,000.³

In reviewing Market Watch, *The Value of Electronic Health Records in Community Health Centers: Policy Implications* by Robert H. Miller and Christopher E. West, the cost and benefits of electronic health records is reported in six community health centers (CHCs) that serve disadvantaged patients.⁴ Robert Miller and Christopher West report that initial EHR costs per full-time-equivalent (FTE) billing provider averaged almost \$54,000, with much variation across CHCs and within each cost category, including hardware, software, installation, training, etc. and ongoing costs per FTE provider, per year, averaged \$20,610.⁵

A Congressional Budget Office (CBO) Paper: *Evidence on the Costs and Benefits of Health Information Technology* from May 2008 indicates that estimating the total cost of implementing HIT systems in office-based medical practices is complicated by differences in the types and available features of the systems now being sold, as well as differences in characteristics of the practices that adopt them. The CBO paper goes further to say that few detailed studies available report that total costs for office-based EHRs are

about \$25,000—\$45,000 per physician⁶ and estimates for annual costs for operating and maintaining the system, which include software licensing fees, technical support, and updating and replacing used equipment range between \$3,000 to \$9,000 per physician per year.⁷

An article written by the Agency for Healthcare Research and Quality (AHRQ), *Research Activities*, September 2005, *Health Information Technology*, adoption rates of electronic health records are low among physician groups—indicates that the average purchase and implementation cost of an EHR was \$32,606 per FTE physician. The article indicates that maintenance costs were an additional \$1,500 per physician, per month and smaller practices had the highest implementation costs per physician at \$37,204.⁸

In conducting a review of the data, we determined that the studies demonstrate a cross-sectional view of small and large practices and community health centers. There was adequate data to support a depiction of costs across multiple provider types.

To summarize, we determined that the average costs of EHRs vary greatly because of the size and type of provider practices, the differences in available features of systems, and the additional costs associated with licensing, support, training, and maintenance. However, based on the information reviewed, we determined that the average costs for initial EHR systems currently can range from \$25,000 to \$54,000 in the implementation year, per professional. Since the average costs of EHR technology in the first year can be as much as \$54,000 and no less than \$25,000, and since we believe the costs of such technology will be increasing, we are proposing to set the average allowable cost at \$54,000. We believe that to establish this average allowable cost at the high end of the range is reasonable since the data we reviewed is based on certification standards that may not be appropriate moving forward. Specifically, since the ONC will be establishing new certification standards for EHR technology in the coming months, we believe the average cost of certified EHR technology incorporating

the new standards will be higher than the current costs of EHR technology. It is our assumption that making improvements to incorporate the new certification standards into current EHR technology will be costly. Thus, we believe that establishing the average allowable cost at \$54,000 is reasonable.

Additionally, our analysis determined that the range for subsequent incentive payment year costs for most providers will fall into a large range, based on a number of factors. On one end of the range, costs related to maintenance could be as low as \$3,000 to \$9,000 per provider, where other studies state that maintenance will be as high as \$18,000 to \$20,610 per provider. Given the expectations in the ONC interim final rule for system performance, interoperability, and the health measures data discussed in this proposed rule that CMS and the States will need to collect from professionals, we believe that the costs for maintaining certified EHR technology will also be on the higher end of the range at \$20,610.

(3) Net Average Allowable Costs

As required by section 1903(t)(3)(E) of the Act, in order to determine “net” average allowable costs, average allowable costs for each provider must be adjusted in order to subtract any payment that is made to Medicaid EPs and is directly attributable to payment for certified EHR technology or support services of such technology. The only exception to this requirement is that payments from State or local governments do not reduce the average allowable costs. The resulting figure is the “net” average allowable cost; that is, average allowable cost minus payments from other sources (other than State or local governments). The statute indicates that EPs may receive 85 percent of a maximum net average allowable cost in the first year of \$25,000 and a maximum net average allowable cost of \$10,000 in subsequent years. This would mean that, as required by the statute, the net average allowable costs are capped at these amounts.

Since we have proposed that the average allowable cost is \$54,000 in the first year, EPs could receive as much as \$29,000 in funding from sources (other than from State or local governments) as contributions to the certified EHR technology and the incentive payment would still be based on 85 percent of the maximum net average allowable cost of \$25,000 (or \$21,250). This is appropriate since \$54,000 (the average allowable cost) minus \$29,000 (contributing sources of funding from other than State or local governments) equals \$25,000.

² Moshman Associates, Inc., Booz Allen Hamilton, in September 2006—*Assessing the Economics of EMR Adoption and Successful Implementation in Physical Small Practice Settings*, p. 40.

³ Moshman Associates Inc., Booz, Allen, Hamilton, p. 50.

⁴ Market Watch, *The Value of Electronic Health Records in Community Health Centers: Policy Implications* by Robert H. Miller and Christopher E. West, p. 206.

⁵ Market Watch, *The Value of Electronic Health Records in Community Health Centers: Policy Implications* by Robert H. Miller and Christopher E. West, p. 208.

⁶ A CBO Paper, *Evidence on the Costs and Benefits of Health Information Technology*, May 2008, p. 17.

⁷ A CBO Paper, *Evidence on the Costs and Benefits of Health Information Technology*, May 2008, p. 18.

⁸ Agency for Healthcare Research and Quality, *Research Activities*, September 2005, *Health Information Technology*, Adoption rates of electronic health records are low among physician groups.

Since \$25,000 is equal to the level of the maximum net average allowable cost or capped amount discussed above, providers could receive 85 percent of \$25,000 or \$21,250 in year one as a Medicaid incentive payment.

The same logic would hold true for subsequent years. Specifically, if in the following years an eligible professional received as much as \$10,610 in contributing funds from sources other than State or local governments, the maximum incentive payment of \$8,500 would be unaffected in such subsequent years. This result is due to the fact that the average allowable costs of \$20,610 for maintaining EHR technology minus the \$10,610 received would still equal \$10,000, the maximum net average allowable costs permitted under the statute.

In reviewing whether a reduction in the net average allowable cost was warranted based on other contributions to EHR technology, we considered the situation of EPs who may have been provided with the actual certified EHR technology, as well as training, support services, and other services that would promote the implementation and meaningful use of such technology. In some cases, we do not believe the contribution would reduce average allowable costs at all. For example, if an FQHC or RHC has provided technology to its staff EPs to use, we do not believe that such technology provision would be considered a “payment” from another source that would reduce average allowable costs. Moreover, we believe the situations in which an EP has been provided with the actual technology,

support service, or training from another source are extremely limited in light of the statutory prohibitions on “kickbacks” at Section 1128B(b) of the Act.

(4) Payments for Medicaid Eligible Professionals

One important difference we propose between the payments to Medicaid EPs and hospitals is that States would disburse the payments to EPs in alignment with the calendar year, whereas hospitals will receive payments in alignment with the fiscal year, as described in section II.D.4.b. of this proposed rule. There are two primary reasons for this. The first is to align Medicaid incentive payment disbursements with that of the Medicare program, in order to support consistency between the two programs, as well as among the States. We will undertake national outreach activities to encourage provider EHR adoption and to align the annual payment periods. Since meaningful use of the certified EHR technology is the driver of the incentives, we believe that a cooperative approach between CMS, ONC, and the States would be realized with more providers participating in the program.

As previously discussed in this proposed rule, based on the 85 percent threshold applied to the net average allowable costs, we propose that most Medicaid EPs may receive up to a maximum incentive payment of \$21,250 in the first payment year.

In subsequent years of payment, Medicaid EPs’ incentive payments will be limited to 85 percent of the \$10,000

cap on net average allowable cost, or up to a maximum of \$8,500 annually for most Medicaid EPs.

Since pediatricians are qualified to participate in the Medicaid EHR incentive program as physicians, and therefore classified as Medicaid EPs, they may qualify to receive the full incentive (that is, the 85 percent threshold applied to the net average allowable cost) if the pediatrician is not hospital-based and can demonstrate that they meet the minimum 30 percent Medicaid patient volume requirements discussed in this subpart.

Pediatricians who are not hospital-based, and have a minimum of 20 percent of their patient encounters paid by Medicaid are also encouraged to participate in the Medicaid EHR incentive program. The maximum payment amount for these pediatricians, who meet the 20 percent Medicaid patient volume, but fall short of the 30 percent patient volume, is reduced to two-thirds of the net average allowable cost, subject to the 85 percent threshold. The reduction accounts for the reduced patient volume, but the intent is to offer an incentive to attract pediatricians to participate. This means pediatricians with a minimum 20 percent patient volume may qualify for up to a maximum of \$14,167 in the first incentive payment year and up to a maximum of \$5,667 in the 5 subsequent incentive payment years, or no more than \$42,500 over the maximum 6 year period.

Table 27 demonstrates the various maximum incentive payment amounts for Medicaid professionals.

TABLE 27—MAXIMUM INCENTIVE PAYMENT AMOUNT FOR MEDICAID PROFESSIONALS

Cap on net average allowable costs, per the HITECH Act	85 percent allowed for eligible professionals	Maximum cumulative incentive over 6-year period
\$25,000 in Year 1 for most professionals	\$21,250	
\$10,000 in Years 2–6 for most professionals	8,500	\$63,750
\$16,667 in Year 1 for pediatricians with a minimum 20 percent patient volume, but less than 30 percent patient volume, Medicaid patients	14,167	
\$6,667 in Years 2–6 for pediatricians with a minimum 20 percent patient volume, but less than 30 percent patient volume, Medicaid patients	5,667	42,500

(5) Basis for Medicaid EHR Incentive Program First Payment Year and Subsequent Payment Years

(i) Medicaid EP Who Begins Adopting, Implementing or Upgrading Certified EHR Technology in the First Year

A Medicaid EP who begins by adopting, implementing, or upgrading certified EHR technology in the first year will be eligible for the incentive

payments not in excess of the maximum amount. Under section 1903(t)(4) of the Act he or she is eligible to receive up to the maximum first year Medicaid incentive payments discussed in the previous sections, plus additional incentive payments for up to 5 years for demonstrating meaningful use of certified EHR technology. In other words, these providers may participate

in the Medicaid EHR incentive program for up to 6 years.

Table 28 demonstrates the payment scenarios available to a Medicaid EP who begins in their first year by adopting, implementing, or upgrading certified EHR technology. As can be seen from the table, the EP can begin receiving payments as late as 2016, and still receive up to the maximum payments under the program.

TABLE 28—PAYMENT SCENARIOS FOR MEDICAID EPS WHO BEGIN ADOPTION IN THE FIRST YEAR

Calendar year	Medicaid EPs who begin adoption in					
	2011	2012	2013	2014	2015	2016
2011	\$21,250
2012	8,500	\$21,250
2013	8,500	8,500	\$21,250
2014	8,500	8,500	8,500	\$21,250
2015	8,500	8,500	8,500	8,500	\$21,250
2016	8,500	8,500	8,500	8,500	8,500	\$21,250
2017	8,500	8,500	8,500	8,500	8,500
2018	8,500	8,500	8,500	8,500
2019	8,500	8,500	8,500
2020	8,500	8,500
2021	8,500
Total	63,750	63,750	63,750	63,750	63,750	63,750

(ii) Medicaid EP Who Has Already Adopted, Implemented or Upgraded Certified EHR Technology and Meaningfully Uses EHR Technology

For a Medicaid EP who has already adopted, implemented, or upgraded certified EHR technology and can meaningfully use this technology in the first incentive payment year, we propose that the Medicaid EP be permitted to receive the same maximum payments, for the same period of time, as the Medicaid EP who merely adopted, implemented or upgraded certified EHR technology in the first year. Section 1903(t)(6)(C)(ii) of the Act states that for a Medicaid EP or hospital who has completed “adopting, implementing, or upgrading” certified

EHR technology “prior to the first year of payment. * * * clause (i)(I) shall not apply and clause (i)(II) [discussing the demonstration of meaningful use] shall apply to each year of payment to the Medicaid provider under this subsection, including the first year of payment.” We believe this provision supports an interpretation that a Medicaid EP who has already adopted certified EHR technology, would still receive a “first year” of payment under section 1903(t)(4) of the Act, and like all other first years of payment, this payment could not exceed \$21,250. Then, under section 1903(t)(4)(A)(ii) and (iii) of the Act, such Medicaid EPs could receive an additional 5 years of payment for subsequent years of

payment, with payments not exceeding \$8,500 in each of these 5 subsequent years. This approach allows early adopters of certified EHR to begin meaningfully using technology, without being at a competitive disadvantage, and without losing incentive payments for the previous costs associated with adopting, implementing, or upgrading certified EHR technology.

Thus, the maximum incentive payments for Medicaid EPs demonstrating that they are meaningful users in the first payment year, would be identical to the maximum payments available to those demonstrating adoption, implementation, or upgrading certified EHR technology in the first year, as depicted in Table 29.

TABLE 29—MAXIMUM INCENTIVE PAYMENTS FOR MEDICAID EPS WHO ARE MEANINGFUL USERS IN THE FIRST PAYMENT YEAR

Calendar year	Medicaid EPs who begin meaningful use of certified EHR technology in					
	2011	2012	2013	2014	2015	2016
2011	\$21,250
2012	8,500	\$21,250
2013	8,500	8,500	\$21,250
2014	8,500	8,500	8,500	\$21,250
2015	8,500	8,500	8,500	8,500	\$21,250
2016	8,500	8,500	8,500	8,500	8,500	\$21,250
2017	8,500	8,500	8,500	8,500	8,500
2018	8,500	8,500	8,500	8,500
2019	8,500	8,500	8,500
2020	8,500	8,500
2021	8,500
Total	63,750	63,750	63,750	63,750	63,750	63,750

An alternative approach we request comment on would be to limit the incentive payment for Medicaid EPs who have already adopted, implemented, or upgraded certified EHR technology to 5 years of payment, at a maximum payment of \$8,500 per year. This approach would interpret section

1903(t)(4)(A) of the Act, which states that the \$25,000 cap on net average allowable costs is intended to cover the costs of implementing or adopting certified EHR technology, as limiting the \$21,250 payment only to those actually adopting the technology in their first year of payment. While early adopters

would still be eligible to receive incentive payments, the payment totals would be lower, because such adopters would not need an incentive payment in order to actually implement, adopt, or upgrade certified EHR technology. This alternative approach is depicted in Table 30.

TABLE 30—ALTERNATIVE INCENTIVE PAYMENT SCENARIO FOR MEDICAID EPS WHO HAVE ADOPTED EHR TECHNOLOGY BEFORE THE FIRST YEAR

Calendar year	Medicaid EPs who begin meaningful use in					
	2011	2012	2013	2014	2015	2016
2011	\$8,500
2012	8,500	\$8,500
2013	8,500	8,500	\$8,500
2014	8,500	8,500	8,500	\$8,500
2015	8,500	8,500	8,500	8,500	\$8,500
2016	8,500	8,500	8,500	8,500	\$8,500
2017	8,500	8,500	8,500	8,500
2018	8,500	8,500	8,500
2019	8,500	8,500
2020	8,500
2021
Total	42,500	42,500	42,500	42,500	42,500	42,500

Medicaid EPs are not required to participate on a consecutive annual basis. The tables in this section demonstrate how a Medicaid EP would maximize the aggregate incentive under different scenarios, considering that a Medicaid EP may initiate participation in 2011 through 2016. Additionally, these tables do not include the alternative Medicaid maximum incentive payment for pediatricians discussed in the previous section, which is two-thirds of the total amount listed in Tables 27 through 30. Finally, these tables do not represent EPs whose incentive payments may be reduced because net average allowable costs may actually be lower than \$25,000 in the first year, or \$10,000 in subsequent years, due to payments from other, non-State/local sources.

b. Payment Methodology for Eligible Hospitals

Statutory parameters placed on Medicaid incentive payments to hospitals are largely based on the methodology applied to Medicare incentive payments. The specifications described in this section are limits to which States must adhere when developing aggregate EHR hospital incentive amounts for Medicaid-eligible hospitals. States will calculate hospitals' aggregate EHR hospital incentive amounts on the FFY to align with hospitals participating in the Medicare EHR incentive program.

States may pay children's hospitals and acute care hospitals up to 100 percent of an aggregate EHR hospital incentive amount provided over a minimum of a 3-year period and a maximum of a 6-year period. The maximum incentive amounts for these providers are statutorily defined by a formula at section 1903(t)(5)(B) of the Act. The statute requires that Medicaid

refer, with some adjustments, to the calculation for the Medicare hospital incentive payment described at sections 1886(n)(2)(A), 1886(n)(2)(C), and 1886(n)(2)(D) of the Act, to determine the aggregate EHR amount allowable for individual hospitals. The aggregate EHR hospital incentive amount is calculated using an overall EHR amount multiplied by the Medicaid share. The aggregate EHR hospital incentive amount is the total amount the hospital could receive in Medicaid payments over 4 years of the program.

States are responsible for using auditable data sources to calculate Medicaid EPs' aggregate EHR hospital incentive amounts, as well as determining Medicaid incentive payments to those providers. Auditable data sources include—

- Providers' Medicare cost reports;
- State-specific Medicaid cost reports;
- Payment and utilization

information from the State's MMIS (or other automated claims processing systems or information retrieval systems); and

- Hospital financial statements and hospital accounting records.

All State Medicaid EHR incentive program calculations, payments, and limits under this section are subject to our review.

For purposes of the Medicaid EHR incentive program, the overall EHR amount is equal to the sum over 4 years of (I)(a) the base amount (defined by statute as \$2,000,000); plus (b) the discharge related amount defined as \$200 for the 1,150th through the 23,000th discharge for the first payment year (for subsequent payment years, States must assume discharges increase by the provider's average annual rate of growth for the most recent 3 years for which data are available per year); multiplied by (II) the transition factor

for each year equals 1 in year 1, $\frac{3}{4}$ in year 2, $\frac{1}{2}$ in year 3, and $\frac{1}{4}$ in year 4.

The statute specifies that the payment year is determined based on a Federal fiscal year. Section 1886(n)(2)(C) of the Act provides the Secretary with authority to determine the discharge related amount on the basis of discharge data from a relevant hospital cost reporting period, for use in determining the incentive payment during a Federal fiscal year. Federal fiscal years begin on October 1 of each calendar year, and end on September 30 of the subsequent calendar year. Hospital cost reporting periods can begin with any month of a calendar year, and end on the last day of the 12th subsequent month in the next calendar year. For purposes of administrative simplicity and timeliness, we propose that States, for each eligible hospital during each incentive payment year, use data on the hospital discharges from the hospital fiscal year that ends during the Federal fiscal year prior to the fiscal year that serves as the payment year.

Example: FY 2011 begins on October 1, 2010 and ends on September 30, 2011. For an eligible hospital with a cost reporting period running from July 1, 2010 through June 30, 2011, we would employ the relevant data from the hospital's cost reporting period ending June 30, 2010 in order to determine the incentive payment for the hospital during Federal fiscal year 2011. This timeline would allow States to have the relevant data available for determining the aggregate EHR hospital incentive amount in a timely manner for the first and subsequent payment years.

The discharge-related amount is \$200 per discharge for discharges 1,150 through 23,000. To determine the discharge-related amount for the 3 subsequent payment years that are included in determining the overall EHR amount, States should assume discharges for an individual hospital have increased by the average annual growth rate for an individual hospital over the most

recent 3 years of available data from an auditable data source. Note that if a hospital's average annual rate of growth is negative over the 3 year period, it should be applied as such.

We have provided a sample calculation for review that assumes the following:

- An individual provider had 20,000 discharges in the first FY (2011).

- The most recent annual growth data available are as follows:

++ FY 2005 (.028 annual growth rate)

++ FY 2006 (.013 annual growth rate)

++ FY 2007 (.027 annual growth rate)

The average annual growth rate over 3 years = $(.028 \times .013 \times .027)/3 = .0227$.

Year 1

2011 discharge related amount equals:

$(20,000 - 1149) \times \$200 = \$3,770,200$

Year 2

2012 discharge related amount equals:

$20,000 \times 1.0227 = 20,454$

$(20,454 - 1149) \times \$200 = \$3,861,000$

Year 3

2013 discharge related amount equals:

$20,454 \times 1.0227 = 20,918$

$(20,918 - 1149) \times \$200 = \$3,953,800$

Year 4

2014 discharge related amount equals:

$20,918 \times 1.0227 = 21,393$

$(21,393 - 1149) \times \$200 = \$4,048,800$

The overall hospital EHR amount requires that a transition factor be applied to each year. This transition factor equals 1 for year 1, $\frac{3}{4}$ for year 2, $\frac{1}{2}$ for year 3, and $\frac{1}{4}$ for year 4, as provided for in sections 1886(n)(2)(A) and 1886(n)(2)(E) of the Act, and as incorporated through section 1902(t)(5)(B) of the Act. We note that although, for purposes of the Medicare incentives, section 1886(n)(2)(E)(ii) of the Act requires a transition factor of 0, if the first payment year is after 2013, we do not believe this rule would apply in the context of the Medicaid incentive payments. Nothing in section 1903(t) of the Act specifically cross references this 0 transition factor, and, notably, section 1903(t) of the Act allows Medicaid incentive payments to begin as late as 2016.

The "Medicaid Share," against which the overall EHR amount is multiplied, is essentially the percentage of a hospital's inpatient, non-charity care days that are attributable to Medicaid inpatients. More specifically, the Medicaid share is a fraction expressed as—

- Estimated Medicaid inpatient-bed-days plus estimated Medicaid managed care inpatient-bed-days;

- Divided by;

- Estimated total inpatient-bed days multiplied by ((estimated total charges minus charity care charges) divided by estimated total charges).

As indicated in the above formula, the Medicaid share includes both Medicaid inpatient-bed-days and Medicaid managed care inpatient-bed-days. This is in keeping with section 1903(t)(5)(C)

of the Act, which provides that in computing inpatient-bed-days, the Secretary shall take into account inpatient-bed-days that are paid for individuals enrolled in a Medicaid managed care plan under sections 1903(m) or 1932 of the Act. We interpret these managed care individuals to be individuals enrolled in a managed care organization (MCO), prepaid inpatient health plan (PIHP), or prepaid ambulatory health plan (PAHP) under 42 CFR part 438.

Some Medicaid managed care entities (that is, MCOs, PIHPs, and PAHPs with risk contracts) provide substitute services (or, "in-lieu-of services") in more cost effective or efficient settings than the State plan services in the managed care contract. For example, in a hospital inpatient setting, these services could be in a different unit, such as a subacute wing or skilled nursing wing, so long as States and contracting entities are in compliance with the actuarial soundness rules at 42 CFR 438.6(c), provision of substitute services is allowed. Although we understand that these substitute service days may be used to achieve efficiency and cost effectiveness, we do not believe such substitute service days should count as "inpatient-bed-days" in the hospital EHR incentive payment calculation. The statute requires us to calculate the Medicaid share "in the same manner" as the Medicare share under section 1886(n)(2)(D) of the Act and such substitute service days would not be considered "in the same manner." Thus, we propose that for purposes of the Medicaid formula, we would count only those days that would count as inpatient-bed-days for Medicare purposes under section 1886(n)(2)(D) of the Act.

In addition, because the formula for calculating the Medicaid share requires a determination of charity care charges, States should use the revised Medicare 2552–10, Worksheet S–10 or another auditable data source to determine the charity care portion of the formula. In the absence of sufficient charity care data to complete the calculation, section 1886(n)(2)(D) of the Act, requires the use of uncompensated care data to derive an appropriate estimate of charity care, including a downward adjustment for bad debts. We interpreted bad debt to be consistent with the Medicare definition of bad debt as promulgated at 42 CFR 413.89(b)(1).

Finally, per section 1886(n)(2)(D) of the Act, to the extent there is simply not sufficient data that would allow the State to estimate the inpatient bed-days attributable to Medicaid managed care patients, the statute directs that such

figure is deemed to equal 0. Likewise, if there is simply not sufficient data for the State to estimate the percentage of inpatient bed days that are not charity care (that is, [estimated total charges—charity care charges]/estimated total charges), the statute directs that such figure is deemed to equal 1.

The aggregate EHR incentive calculation for Medicaid eligible hospitals is represented mathematically as follows:

$$\begin{aligned} & (\text{Overall EHR Amount}) * (\text{Medicaid Share}) \text{ or} \\ & \{ \text{Sum over 4 year of } [(\text{Base Amount} + \text{Discharge Related Amount Applicable for Each Year}) * \text{Transition Factor Applicable for Each Year}] * \\ & \{ (\text{Medicaid inpatient-bed-days} + \text{Medicaid managed care inpatient-bed-days}) / [(\text{total inpatient-bed days}) * (\text{estimated total charges} - \text{charity care charges}) / (\text{estimated total charges})] \} \end{aligned}$$

To achieve the aggregate EHR hospital incentive amount at 1903(t)(5)(a), the calculation must be aggregated over 4 years. For further clarification, we have provided a sample calculation of the aggregate EHR hospital amount.

Assume the following as constant over 4 years except where noted:

- 20,000 discharges (Note: This calculation assumes the same averaging data calculated in the average annual growth example above.)

- 34,000 inpatient Medicaid bed-days (including fee-for-service and managed care days)

- 100,000 total inpatient bed-days
- \$1,000,000,000 in total charges
- \$200,000,000 in charity care
- Overall EHR amount = Sum (Year 1, Year 2, Year 3, Year 4) = \$14,655,050

Year 1: $\{ \$2,000,000 + ((20,000 - 1,149) \times 200) \} \times 1 \times 1 = \$5,770,200$

Year 2: $\{ \$2,000,000 + ((20,454 - 1,149) \times 200) \} \times 1 \times .75 = \$4,395,750$

Year 3: $\{ \$2,000,000 + ((20,918 - 1,149) \times 200) \} \times 1 \times .50 = \$2,976,900$

Year 4: $\{ \$2,000,000 + ((21,393 - 1,149) \times 200) \} \times 1 \times .25 = \$1,512,200$

Medicaid Share: $34,000 / (100,000 \times ((\$1,000,000,000 - \$200,000,000) / 1,000,000,000)) = 0.425$

Overall EHR Amount \times Medicaid Share = Medicaid aggregate EHR incentive amount $\$14,655,050 \times 0.425 = \$6,228,396$

Unlike Medicaid EPs, who must waive rights to duplicative Medicare incentive payments, hospitals may receive incentive payments from both Medicare and Medicaid, contingent on successful demonstration of meaningful use and other requirements under both programs.

The last year that a hospital may begin receiving Medicaid incentive payments is FY 2016. States must make payments over a minimum of 3 years and a maximum of 6 years. Additionally, in any given payment year, no annual Medicaid incentive payment to a hospital may exceed 50

percent of the hospital's aggregate incentive payment. Likewise, over a 2-year period, no Medicaid payment to a hospital may exceed 90 percent of the aggregate incentive.

Table 31 demonstrates several scenarios for Medicaid hospitals. However, there are other scenarios not

included here. For example, this table assumes that a hospital would participate on a consecutive annual basis until the incentive is exhausted. The purpose of Table 31 is to illustrate the general timeline for Medicaid hospital incentives.

TABLE 31: Hospital Incentives

States will monitor compliance of hospitals coming onto the program with different requirements depending on the year. Incentive determination will also be based on Y1 versus subsequent years. This chart is an example, noting that hospitals may collect the incentive over 3-6 years.							
←← Becomes more difficult to establish meaningful use.	CY	Demonstration of Compliance					
	2011	Y1	Y1 participants must demonstrate that they engaged in efforts to adopt, implement, or upgrade to certified EHR technology. However, if users already adopted, they may proceed to Y2 requirements in Y1.				
	2012	Y2	Y1	Y1, same as above. Y2 must become a meaningful EHR user. We expect to issue definition of meaningful use on a biannual basis beginning in 2011.			
	2013	Y3	Y2	Y1	Y1, same as above. Y2-3 will be the same.		
	2014	Y4	Y3	Y2	Y1	Y1, same as above. Y2-4, same as above.	
	2015	Y5	Y4	Y3	Y2	Y1	Y1, same as above. Y2-5, same as above.
	2016	Y6	Y5	Y4	Y3	Y2	Y1, same as above.
	2017		Y6	Y5	Y4	Y3	Y2, same as above.
	2018			Y6	Y5	Y4	Y3, same as above.
	2019				Y6	Y5	Y4, same as above.
	2020					Y6	Y5, same as above.
	2021						Y6, same as above.

c. Alternative and Optional Early State Implementation to Make Incentive Payments for Adopting, Implementing, or Upgrading Certified EHR Technology

Unlike Medicare, Medicaid has no statutory implementation date for making EHR incentive payments. We believe that some States may be prepared to implement their program and make EHR incentive payments to Medicaid providers in 2010 for adopting, implementing, or upgrading certified EHR technology. We propose to allow States to initiate implementation of these payments to Medicaid EPs and hospitals after promulgation of the final rule if they successfully demonstrate to CMS that they are ready to make timely and accurate payments through the

SMHP. States should include an additional attestation for providers assuring that they are not accepting payment in any other State.

In order for us to approve a State for early implementation, we are proposing that a State would have an electronic system for provider registration capable of collecting the relevant information identified in section II.A.5.c of this proposed rule, where we describe the data collection requirements. This includes the following:

- Name, National Provider Identifier (NPI), business address and business phone of each EP or eligible hospital;
- Taxpayer Identification Number to which the EP or eligible hospital wants the incentive payment made;

- For eligible hospitals, their CMS Certification Number (CCN);

- The remittance date and amount of any incentive payments made to an EP or eligible hospital.

Participating States would be responsible for transmitting this data to CMS so that CMS can ensure that no duplicate payments will be made to providers. We would use the single provider election repository described in section II.A.5.c. of this proposed rule to assure no duplicative payments were made between States.

We are not proposing that States would be able to make early payments to meaningful users. This opportunity is intended to offer Medicaid providers an early opportunity for capital so that they are more likely to have the certified EHR

technology required to demonstrate meaningful use in successive periods. Since hospitals may qualify under both programs, we hope that they will use the capital and qualify as a meaningful user under the Medicare program in the first year. We are requesting comments on this proposed approach.

d. Process for Making and Receiving Medicaid Incentive Payments

The process for making payments involves coordination between Medicare and State Medicaid agencies to avoid duplication of payments, prevent fraud and abuse, and create program efficiencies to encourage adoption. While we have responsibility regarding payments to Medicare EPs and hospitals, State Medicaid agencies (or their contractors) are fully responsible for administering and disbursing the incentive payments to Medicaid providers.

We will require that EPs make a selection between receiving incentive payments through either the Medicare or Medicaid EHR incentive programs. Medicaid EPs who practice in multiple states will be required to choose only one state from which to receive Medicaid incentive payments. The issues related to these decisions are discussed here, as well as in section II.A of this proposed rule.

In this section, we describe the steps Medicaid EPs will take to receive an incentive payment. Due to the interdependencies of multiple issues, we refer the reader to other sections of this proposed rule. Specifically, section II.A of this proposed rule solicits comments for a proposed reporting period in the first payment year of any continuous 90-day period that starts and ends within the calendar year. In addition, such 90-day period would apply in both the first and second payments years (that is, 2010 and 2011) for States approved for early implementation in 2010. Section II.A. also solicits comments on full annual reporting periods for all payment years other than the first payment year (except in the case of States approved for 2010 implementation, for which the full annual reporting period would begin in the third year). We also discuss the proposed single provider election repository and other issues impacting both programs.

It is important to note that there is a very clear intent in the statute that there is coordination between the EHR incentive programs to reduce or eliminate duplicate payments between Medicare and Medicaid. Additionally, Medicare requirements under section 1848(o)(1)(B) of the Act require that payments begin no earlier than 2011.

While the Medicaid provisions have no statutory start date, before States may begin implementing the Medicaid EHR incentives, CMS, and ONC need to provide guidance to States in the form of rulemaking and other policy guidance. To that end, Medicaid will not begin to provide 100 percent FFP for incentive payments any earlier than FY 2011 for hospitals and CY 2011 for EPs, (except in the case of incentive payments for adopting, implementing, or upgrading, which could begin in 2010. See discussion in section II.D.4.b.(5).c) of this proposed rule. This also gives CMS, ONC, and States an opportunity to coordinate between Medicare and Medicaid, which we hope will simplify administrative complexity in the EHR incentive program and facilitate provider adoption.

We believe that by aligning the EHR incentive programs where possible, Medicaid EHR incentive program administration could be more efficient for the States, and provider communication about the program could be less ambiguous. This will be of particular benefit to the providers who serve both Medicare and Medicaid program beneficiaries, and will be eligible for participation in both incentive programs. Also, we believe that the incidence of fraud and abuse could be curtailed, and the potential for duplication of payments could be decreased.

Under this proposed rule we are proposing that Medicaid EPs, as discussed in section II.D.5 and II.A.5.c of this proposed rule, will enroll in the program through the single provider election repository. Once an EP selects the Medicaid EHR incentive program, we propose that States must have a system for reporting and tracking necessary information to qualify an EP for an incentive payment. In addition, as detailed in § 495.316 States will be required to submit data to CMS including data for the number, type and practice location(s) of providers who qualified for an incentive payment on the basis of having adopted, implemented, or upgraded certified EHR technology or who qualified for an incentive payment on the basis of having meaningfully used such technology as well as aggregate de-identified data on meaningful use. States' systems and processes will be submitted by the States to CMS for prior approval, concurrent with the requirements described in section II.D.8 of this proposed rule for review and approval of the SMHP.

The specific timeframes for EPs and eligible hospitals to report and submit the required information in order to

demonstrate they have adopted, implemented, or upgraded certified EHR technology, as well as meaningful use of such EHR technology are proposed for comment at section II.A.1.e of this preamble. As discussed in that section of this proposed rule, for the first payment year (as well as the second payment year for those hospitals that are able to begin receiving payments for FY 2010), the reporting periods for eligible hospitals will be on a continuous 90-day basis, in the sense that as long as the start and end dates occur within the payment year and as long as the period spans the proposed 90-day consecutive period, the period can begin at any time during the payment year. States will then be expected to process payments, also on a rolling basis. In the subsequent payment years, the reporting period will be a full annual period (that is, a full payment period).

e. Avoiding Duplicate Payment

At section 1903(t)(7) of the Act, the statute requires that the Medicare and Medicaid programs coordinate payments to avoid duplication. This section further specifies that CMS and the States should coordinate payments through a data matching process, utilizing NPIs to the extent practicable. Additionally, section 1903(t)(2) of the Act states that Medicaid EPs must waive rights to Medicare incentive payments under sections 1848(o) and 1853(l) of the Act. As previously noted, hospitals may qualify for incentives under both programs. We also propose requirements under the review and approval of SMHPs in proposed part 495 subpart D for States to verify that providers meet these requirements.

As discussed in section II.A of this proposed rule, we considered what information will be necessary to eliminate duplicative incentive payments to providers between the Medicare and Medicaid programs. In order to ensure against duplicate incentive payments, we believe three conditions are required: (1) Knowing which EHR incentive program a provider has selected, (2) uniquely identifying each provider participating in each incentive program; and (3) ensuring that each State has access to the information on which EPs or hospitals intend to receive incentive payments from another State, or from the Medicare program.

To achieve all three of these conditions, as discussed in section II.A.5.c of this proposed rule, we propose to collect this data in a single provider election repository. Next, in administering each State Medicaid EHR incentive program, we propose that

States would cross-check for potential duplicative payments through the data available to them through the single provider election repository, which is based on the NPIs. We believe that this coordinates with our proposed requirements that a State must have an approved SMHP which will include a mechanism for cross-checking this information prior to payment.

f. Flexibility To Alternate Between Medicare and Medicaid EHR Incentive Programs One Time

We refer readers to section II.A.5.b of this proposed rule, where we discuss our proposal to allow Medicare and Medicaid EPs to make one EHR incentive program election change prior to 2015, and not to permit any switching after the year 2014. Under such a proposal, even if an EP initially received incentive payments under the Medicare program, such an EP could still switch to the Medicaid program one time prior to 2015. Similarly, an EP who initially selected the Medicaid EHR incentive program could switch to the Medicare program one time prior to 2015.

g. One State Selection

We propose that for EPs and hospitals with multi-state Medicaid practice locations, that the provider may annually pick only one State from which to receive incentive payments. In other words, a provider would not be able to receive incentive payments from more than one State in the same year. For example, a provider may be licensed to practice in Illinois as well as in Iowa, particularly in the area known as the Quad Cities because of the multiple cities in proximity to the Illinois and Iowa borders. There are numerous situations like this throughout the country for States sharing borders. Medicaid EPs and hospitals may change the State that they select annually when they re-attest to the program requirements.

Since qualifying for the Medicaid incentive payments is not a claims accrual process, as it is in Medicare, allowing providers to include multiple practice sites across State boundaries would create enormous administrative complexity for both CMS and State Medicaid agencies. For example, States would have to collect and verify Medicaid patient volume across more than one State, then divide and administer payments based on a methodology suitable between the State Medicaid agencies and the providers. Given that the providers qualifying for the Medicaid incentive program will receive the same incentive payment dollar amount regardless of whether

payments are made by one, or more than one, State, we believe it would not be worth the resulting administrative complexity to allow payments from multiple States.

We considered the possible impact of this proposed approach with respect to patient volume calculations on Medicaid EPs and hospitals in border State areas. While we addressed the administrative complexity of this issue here, we recommend that States consider these border State providers when developing their policies and attestation methodology. We afforded additional flexibility in the patient volume at proposed § 495.306 to account for unique circumstances and data collection.

5. Single Provider Election Repository and State Data Collection

We refer readers to section II.A.5.c of this proposed rule for a discussion of the single provider election repository. As discussed in that section, the repository will collect a minimum amount of information on all EPs and hospitals to prevent duplicative payments and coordinate technical assistance.

6. Collection of Information Related to the Eligible Professional's National Provider Identifier and the Tax Identification Number

Similar to the policy proposed where Medicaid EPs and hospitals must select one State, for those EPs in multiple group practices or multiple types of practice locations, we propose to require such professionals to select one TIN for Medicaid EHR payment disbursement. In other words, such EPs could not require a State to divide payments among different practices or practice locations based upon group TINs. Requiring EPs to use only one TIN would reduce administrative complexity, as it would ensure that States are not put in the position of dividing payments in any way an EP requests (such as by patient encounters or amount contributed to EHR technology). We also believe that requiring reimbursement to be made to one TIN would reduce opportunities for fraud or abuse, as States will be able to cross-check EP and TIN combinations more easily to verify EP attestations.

Although the State would not divide payments among the various TINs of an individual EP, Medicaid EPs could decide to divide payment themselves, and distribute funds among their respective group practices or practice locations after the initial disbursement from the State to their designated TIN.

7. Activities Required To Receive Incentive Payments

• a. General Overview.

As previously discussed, for Medicaid providers (including both EPs and eligible hospitals) to qualify to receive a first year Medicaid incentive payment, section 1903(t)(6)(C)(i) of the Act indicates that the provider must demonstrate that they are “engaged in efforts to adopt, implement, or upgrade certified EHR technology.” For providers who meet this standard in their first year of participation in the Medicaid incentive program, in subsequent years of participation, they must then demonstrate “meaningful use of certified EHR technology through a means that is approved by the State and acceptable to the Secretary,” and that may be based upon the methods employed under the Medicare incentive payments to physicians and hospitals, per sections 1848(o) or 1886(n) of the Act.

• b. Definitions Related to Certified EHR Technology and Adopting, Implementing or Upgrading Such Technology.

(1) Certified EHR Technology

As noted previously, in order to receive a Medicaid incentive payment the EHR technology must be “certified.” Section 1903(t)(3) of the Act defines “certified EHR technology” as a qualified electronic health record (as defined in section 3000(13) of the PHS Act) that is certified pursuant to section 3001(c)(5) of the PHS Act as meeting standards adopted under section 3004 of the PHS Act that are applicable to the type of record involved (as determined by the Secretary), such as an ambulatory electronic health record for office-based physicians or an inpatient hospital electronic health record for hospitals). In section I.A of this proposed rule, for both Medicare and Medicaid, we discussed incorporating ONC's definition of certified EHR technology.

(2) Adopting, Implementing or Upgrading

Unlike the Medicare incentive programs, the Medicaid program allows eligible providers to receive an incentive payment even before they have begun to meaningfully use certified EHR technology. These providers may receive a first year of payment if they are engaged in efforts to “adopt, implement, or upgrade” to certified EHR technology. In proposed § 495.302, we define adopting, implementing or upgrading certified EHR technology as the process by which providers have installed and commenced utilization of certified EHR

technology capable of meeting meaningful use requirements; or expanded the available functionality and commenced utilization of certified EHR technology capable of meeting meaningful use requirements at the practice site, including staffing, maintenance, and training.

For the purposes of demonstrating that providers adopted, implemented, or upgraded certified EHR technology, Medicaid EPs and hospitals would have to attest to having adopted, (that is, acquired and installed) or commenced utilization of (that is, implemented) certified EHR technology; or expanded (that is, upgraded) the available functionality of certified EHR technology and commenced utilization at their practice site. States would be responsible for ensuring that processes are in place to verify that providers have actually adopted, implemented or upgraded certified EHR technology, patient volume, as well as other requirements in this section, including verifying that attestations are consistent with methodologies to combat fraud and abuse (see proposed § 495.366 through 370, Financial Oversight, Program Integrity, and Provider Appeals). The State's SMHP must detail these processes.

The CMS Medicaid Transformation Grants have demonstrated the many challenges that exist to adopting EHR technology. EHR system availability is not the same as EHR system utilization. It is for that reason that we propose to include staff training and efforts to redesign provider workflow under the definition of implementing certified EHR technology. Success is not simply defined by the acquisition and installation of new or upgraded certified EHR technology, but more importantly by providers demonstrating progress towards the integration of EHRs into their routine health care practices to improve patient safety, care, and outcomes.

In establishing criteria for the "adoption" portion of the "adopt, implement, or upgrade" requirement, we propose that there be evidence that a provider demonstrate actual installation prior to the incentive, rather than "efforts" to install. This evidence will serve to differentiate between activities that may not result in installation (for example, researching EHRs or interviewing EHR vendors) and actual purchase/acquisition or installation. It is the States' responsibility to verify this evidence of EHR adoption. As these Medicaid incentive payments are intended to stimulate meaningful use of EHR technology, they need to result in

tangible adoption, implementation, or upgrading of certified EHR technology.

In establishing criteria for the "implementation" portion of "adopt, implement or upgrade" requirement, we are proposing that "implementation" mean that the provider has installed certified EHR technology and has started using the certified EHR technology in his or her clinical practice. Implementation activities would include staff training in the certified EHR technology, the data entry of their patients' demographic and administrative data into the EHR, or establishing data exchange agreements and relationships between the provider's certified EHR technology and other providers, such as laboratories, pharmacies, or HIEs.

In establishing the criteria for the "upgrade" portion of "adopt, implement or upgrade" requirement, we propose "upgrade" to mean the expansion of the functionality of the certified EHR technology, such as the addition of clinical decision support, e-prescribing functionality, CPOE or other enhancements that facilitate the meaningful use of certified EHR technology. States must describe the process that would be in place in the SMHP for ensuring that providers have actually adopted, upgraded or implemented certified EHR technology. We encourage States to consider the submission of a vendor contract from providers to ensure the existence of EHR technology.

In listening sessions with State Medicaid Agencies' staff and Governors' offices staffs, States suggested verifying providers' adoption, implementation, or upgrading of certified EHR technology through system enhancements that track and audit providers' written or electronic attestations, through surveys, or through new claims codes that would serve as attestations. Additional suggestions from State staff included using EHR vendor audit logs for Medicaid EPs rendering service through the FQHCs and tracking EHR reporting of the Health Resources and Services Administration (HRSA)-mandated quality indicators. More information on feedback received as a result of these listening sessions can be found in section II.A. of this proposed rule. These suggestions may be relevant to the discussion below concerning the States process for developing a SMHP, verifying attestations and ensuring that providers are eligible to participate in the incentive payments program.

c. Other General Terminology

"EHR reporting period" and "payment period" relate to the requirements for

Medicaid EPs participating in the Medicaid EHR incentive program. As discussed previously, the reporting period is significant for EPs and eligible hospitals because it will define the period during which the provider must establish efforts to adopt, implement, or upgrade certified EHR technology, or demonstrate meaningful use of, such technology. The reporting period also is significant for States, because States will refer to such reporting periods in assuring us that providers are eligible to participate in the Medicaid EHR incentive program. (Requirements relating to the components that must be included in the SMHP are specified in proposed § 495.354). States will need to refer to the providers' reports of the activities that establish their efforts to adopt, implement, or upgrade certified EHR technology. Similarly, once meaningful use of EHR technology is required to include the reporting of clinical quality measures, States will need to ensure such measures are reported in accordance with the appropriate period. States could not appropriately make incentive payments in the absence of such reporting.

As discussed in section II.A of this proposed rule and elsewhere in this section, we propose that the EHR reporting period would occur on a rolling basis during the first payment year (and also in 2010 for States approved for early implementation). For subsequent payment years, the EHR reporting period will be on an annual basis (that is, for the entire payment year).

States would be required to validate to us that the Medicaid EPs and hospitals meet all of the eligibility criteria to qualify for Medicaid incentive payments, including the applicable patient volume thresholds, hospital-based requirements, and all of the requirements described in this section. States would develop their own administration, payment and audit processes, and as described in § 495.332, we would require that States include in their SMHPs how they would obtain Medicaid EPs' and hospitals' attestations of eligibility to qualify for the Medicaid incentive payments. Permissible means for ensuring patient volume and all of the requirements described in this section include survey, attestation, or the creation of special codes on claims, subject to our prior approval.

Additionally, we may require a more robust method for ensuring compliance with the requirements listed in this section beyond attestation as this program matures. Therefore, we are soliciting comments, including the

impact that an alternative method may have on providers and States if an alternative method that is not attestation is required.

Section 1903(t)(6)(C)(ii) of the Act also indicates that in the case of an early adopter, that is, a Medicaid EP or eligible hospital that has already adopted certified EHR technology, such provider would receive payment in the first year and all subsequent years of the incentive program by demonstrating meaningful use. In other words, such a provider would not need to demonstrate that it has adopted, implemented, or upgraded certified EHR technology in year one of the program, if they can already demonstrate meaningful use of such technology. In the case of Medicaid EPs, we discuss our proposal approach to paying early adopters in section II.D.4.5.

It is expected that the bar for demonstrating meaningful use of certified EHR technology will rise in years to come, as discussed in section II.A. States have offered their suggestions to us as to how they would verify providers' meaningful use of certified EHR technology, including participation in the exchange of clinical and administrative data; National Committee for Quality Assurance (NCQA) certification as an advanced medical home (which includes an EHR requirement); e-prescribing, and conducting security and privacy audits. Many of these elements are discussed in the definition of "meaningful use" noted in section II.A.2. of this proposed rule. For purposes of participation in the Medicaid EHR incentive program, the

specific definition of "meaningful use" in section II.A.2. of this proposed rule is what providers must demonstrate to the States, and what States must track and validate. States wishing to ask providers to demonstrate additional objectives to the definition of "meaningful use" as noted in this proposed rule would need to request our prior approval of such a revised definition in their SMHP, as described in section II.D.8 of this proposed rule.

We do not wish to see the bar for demonstration of meaningful use set so high, especially in the early years of this program that, it becomes a deterrent for broad provider participation. Examples of how States may consider adding to the Federal definition of meaningful use include requiring providers to participate in a health information exchange, and requiring that providers link to immunization, lead screening, or newborn screening registries. These mechanisms must be readily available to providers, and not represent a financial burden for participation. For example, States are discouraged from proposing additional meaningful use measures that would require providers to assume additional financial costs in order to qualify to participate in the Medicaid EHR incentive program.

States should carefully consider how to build upon their existing EHR activities and infrastructure without deterring eligible Medicaid providers from participating by compelling them to use a particular system. We encourage States that were awarded Federal HIT/EHR grants, such as the Medicaid Transformation Grants, to

work to connect the tools and infrastructure developed under their Federal grant funds with providers' efforts to adopt, implement, and upgrade certified EHR technology and to become meaningful users of certified EHR technology. We would be evaluating States' HIT Planning Advanced Planning Documents (PAPDs) and SMHP with this objective in mind, as described in section II.D.8 of this proposed rule.

The requirements to which States would hold eligible Medicaid providers accountable would vary based upon the number of years an eligible Medicaid provider participates in the program. In other words, regardless of the calendar year, a provider's first year as a participant in the Medicaid EHR incentive program is when that provider must demonstrate either adoption, implementation, upgrading or meaningful use of certified EHR technology. States' systems must be able to track providers' year of entry into the Medicaid EHR incentive program to determine the correct eligibility criteria and generate the appropriate Medicaid incentive payments.

In Table 32, we depict the requirements for eligible Medicaid professionals and hospitals that either adopt, implement, or upgrade certified EHR technology or that move directly to meaningful use of such technology. Additionally, we refer readers to Table 1 since the table references the stages of meaningful use. Readers may find this information helpful when considering the information in Table 32.

TABLE 32: Requirements for EPs Over Time to Demonstrate Eligibility for Incentive Payments

		States will monitor compliance of providers coming onto the program with different requirements depending on the year. Incentive determination will also be based on Y1 vs. subsequent years.					
	CY	Demonstration of Compliance					
←←←← Becomes more difficult to establish meaningful use.	2011	Y1	Y1 users must demonstrate that they engaged in efforts to adopt, implement, or upgrade to certified EHR technology. However, if users already adopted, they may proceed to Y2 requirements in Y1.				
	2012	Y2	Y1	Y1, same as above. Y2 must become a meaningful EHR user. We expect to issue definition of meaningful use on a biannual basis beginning in 2011.			
	2013	Y3	Y2	Y1	Y1, same as above. Y2-3 will be the same.		
	2014	Y4	Y3	Y2	Y1	Y1, same as above. Y2-4, same as above.	
	2015	Y5	Y4	Y3	Y2	Y1	Y1, same as above. Y2-5, same as above.
	2016	Y6	Y5	Y4	Y3	Y2	Y1, same as above. Y2-6, same as above.
	2017		Y6	Y5	Y4	Y3	
	2018			Y6	Y5	Y4	
	2019				Y6	Y5	
	2020					Y6	
	2021						Y6

As previously noted, States would be required to verify providers' meaningful use of certified EHR technology. We also expect to test the reporting of additional clinical quality measures that may be used in future definitions of meaningful use. States may wish to participate in this testing and seek out eligible Medicaid providers to report on specific clinical quality measures, extractable from EHRs. States would be able to use this reporting to pilot-test requirements that could be included in future definitions of meaningful use.

Once States are giving providers the Medicaid HIT incentive payments for being meaningful users of EHRs, and starting in 2012 are collecting those providers' clinical quality measures data, States will be required to share any such reported data with CMS in an aggregated, de-identified manner, on an annual basis. The timetable and format for sharing the clinical quality measurement data would be provided to States in future policy guidance issued by CMS. States' failure to submit these required reports to us could result in

discontinued funding or disallowances. See the discussion below regarding the SMHP and the State reporting requirements. We would use the States' reports, including data on meaningful use and clinical quality measures, in order for the Secretary to fulfill her responsibilities to Congress under section 1903(t)(10) of the Act. This provision requires that the Secretary report to Congress on the improvement of health outcomes, clinical quality, or efficiency as a result of implementing this program. For hospitals eligible for both Medicare and Medicaid EHR incentive programs, where hospitals are reporting meaningful use measures to CMS, we will make quality data on Medicaid eligible hospitals available to States.

d. Quality Measures

We refer readers to section II.A.3 of this proposed rule for a discussion of the clinical quality measure reporting required for demonstrating meaningful use of certified EHR technology. As discussed in that section we have

proposed in II.A.3 of this proposed rule, additional clinical quality measures that could be used by Medicaid providers to meet the quality reporting aspect of meaningful use. These additional indicators address key Medicaid services, such as pediatrics, obstetrical/gynecologic, mental health and substance abuse services. Medicaid providers could report on these clinical quality indicators in lieu of the quality indicators that are listed in Table 3. We recognize that quality measures associated with the Stage 1 definition of meaningful use contain certain gaps for Medicaid providers, including in the areas of oral health, long-term care, newborn screening, and other areas of pediatric care. As discussed previously, we intend to update our definition of meaningful use biannually, and we expect that our updated, Stage 2 definition would include additional Medicaid clinical quality measures to be reported from EHRs. We intend to work with the quality measurement community to develop these Stage 2

quality measures (see section II.B.1.d. of this proposed rule).

8. Overview of Conditions for States To Receive Federal Financial Participation (FFP) for Incentive Payments and Implementation Funding

Section 1903(a)(3)(F) of the Act provides that States are eligible for 100 percent FFP for direct payment expenditures to certain Medicaid EPs and eligible hospitals to encourage the adoption and use of certified EHR technology. States are also eligible for 90 percent FFP for reasonable administrative expenses, contingent on State compliance with the following requirements: (1) Using the funds to administer Medicaid incentive payments for certified EHR technology, including tracking of meaningful use by Medicaid EPs and eligible hospitals; (2) conducting oversight of the Medicaid EHR incentive program, including routine tracking of meaningful use attestations and reporting mechanisms; and (3) pursuing initiatives to encourage the adoption of certified EHR technology for the promotion of health care quality and the exchange of health care information.

This section of the proposed rule discusses the requirements for States to request FFP from CMS for the Medicaid EHR incentive program. Additionally, this section is closely connected to the requirements outlined in Financial Oversight, Program Integrity and Providers Appeals for purposes of oversight and accountability.

In proposed § 495.302, we define terms used in the Medicaid subpart of the regulations governing State requests for FFP. Although some of these terms have been defined in other portions of our regulations, for ease of reference, and in order to define the terms in this specific context, we have separately included definitions in part 495. Other terms such as “HIT PAPD,” “IAPD,” “SMHP” are new terms which would be used in approving State plans for FFP.

- **Acceptance Documents:** The term “acceptance document” refers to written evidence of satisfactory completion of an approved phase or work or contract related to information technology projects for which approved Federal funding is utilized. The term is commonly used in information technology projects and is defined in this proposed rule to ensure that we are able to receive information from the State necessary to evaluate and monitor the progress of HIT projects requested or approved under this proposed rule.

- **Acquisition:** The term “acquisition” is defined in this proposed rule to indicate a State’s intent to acquire

health information technology equipment or services for the purpose of implementation and administration of the provisions under this proposed rule from commercial sources or from State or local government resources. We define and utilize this term in the context of HIT planning and implementation activities that will enable States to implement existing Federal requirements for competitive procurement of equipment or services.

- **Service Oriented Architecture:** The term “service oriented architecture” is defined in this proposed rule as a means of organizing and developing information technology capabilities as collaborating services that interact with each other based on open standards. We are defining this term in the context of HIT projects authorized under the HITECH Act to ensure that different systems and programming languages provide the basis for interoperability among and between applications that may reside on different platforms through a communication protocol to achieve health information exchange required under ARRA.

- **State Self-Assessment:** The term “State self assessment” uses a standard methodology and tools to document the way a State conducts business now and plans to conduct business in the future.

- **Medicaid information technology architecture (MITA)** is both an initiative and a framework. It is a national framework to support improved systems development and health care management for the Medicaid enterprise. It is an initiative to establish national guidelines for technologies and processes that enable improved program administration for the Medicaid enterprise. The MITA initiative includes an architecture framework, models, processes, and planning guidelines for enabling State Medicaid enterprises to meet common objectives with the framework while supporting unique local needs.

- **Medicaid management information system (MMIS)** means a mechanized claims processing and information retrieval system—referred to as Medicaid Management Information Systems (MMIS)—that meets specified requirements and that the Department has found (among other things) is compatible with the claims processing and information retrieval systems used in the administration of the Medicare program. The objectives of the MMIS are to include claims processing and retrieval of utilization and management information necessary for program administration and audit and must coordinate with other mechanized systems and subsystems that perform

other functions, such as eligibility determination.

We are defining the “Medicaid Management Information System” as it relates to the mechanized claims processing systems at 42 CFR 433, Subpart C, since this term has not previously been codified in regulations and we are requiring that in implementing this program under the authority of section 1903(t)(6)(D) of the Act, certified EHR technology must be compatible with the MMIS. Additionally, we expect States would align their Medicaid EHR initiatives with those envisioned under MITA, in order to fully support the meaningful use of EHR envisioned under this new program. As part of their SMHP, States will be required to map different IT solutions to their existing Medicaid enterprise business requirements using the MITA business areas and processes list when preparing a baseline State self-assessment. Using the MITA State self-assessment provides a baseline that will facilitate collaboration between the States and CMS, between the State and industry and among the States themselves. The MITA “State self-assessment” process uses a standard methodology and tools to document the way a State conducts business now, and plans to conduct business in the future. The purpose of the SMHP is to identify the “As Is” state and “To Be” (target) state of a State’s Medicaid business enterprise and to align business areas and processes in the user community. Once this alignment is complete, States may then add other Medicaid business processes by extending the MITA model during implementation to ultimately facilitate the EHR program. The State self-assessment would help to identify duplicative and overlapping business areas and processes and to identify gaps by adopting new business areas and processes needed to complete the EHR enterprise. Using an incremental approach and setting achievable goals for the near and mid term, would help the State assess its progress and identify targets of opportunity critical to achieving the long-term “To Be” vision for HIT by 2014.

Further, the Medicaid enterprise is comprised of internal and external communities of common business areas that share an interest in seeing that the mission and goals of the Medicaid program and improved health outcomes are achieved. These communities include the EPs and hospitals that would be receiving incentive payments. MITA’s principles and tools fosters nationally integrated business and IT transformation. It does this by demonstrating that planned

enhancements support State and Medicaid strategic goals and how intra-state systems other than the MMIS have been considered in developing the solutions. By documenting the analysis of alternative solutions, particularly a review of solutions in other States or a description of data sharing components and the reasons to include them or exclude them at this time can then be considered in its solution.

As such, the MITA process establishes the guidelines necessary for EHRs implemented as a result of the Medicaid EHR incentive program to be interoperable with State Medicaid systems, and we believe that as States and providers implement EHRs, it is essential to plan technology upgrades that would facilitate health information exchange with Medicaid providers receiving incentive funding.

- State Medicaid Health Information Technology Plan (SMHP) means a document that describes the State's current and future HIT activities in support of the Medicaid EHR incentive program.

- Health Information Technology Planning Advance Planning Document (HIT PAPD) (and any necessary update documents) means a plan of action that requests FFP and approval to accomplish the planning necessary for a State agency to determine the need for and plan the acquisition of HIT equipment or services or both and to acquire information necessary to prepare a HIT implementation advanced planning document or request for proposal to implement the State Medicaid HIT Plan.

- Health Information Technology Implementation Advance Planning Document (HIT IAPD) (and any necessary update documents) means a plan of action that requests FFP and approval to acquire and implement the proposed State Medicaid HIT Plan services or equipment or both.

To qualify to receive FFP for administering the incentive program, States must develop a SMHP, an HIT PAPD, and an HIT IAPD. These documents would lay out the process States will use to implement and oversee the EHR incentive program, and would help States to construct an HIT roadmap to develop the systems necessary to support providers in their adoption and meaningful use of certified EHR technology. The development of a SMHP (see also § 495.332) provides States with the opportunity to analyze and plan for how EHR technology, over time, can be used to enhance quality and health care outcomes and reduce overall health care costs. The uses of EHR technology can

be integrated with existing State resources to achieve these goals.

We provided guidance in a State Medicaid Director's letter on September 1, 2009, on this process and the State efforts necessary to receive the 90 percent FFP. As previously noted, as States begin the process of developing their SMHPs, they also can begin to receive the 90 percent FFP funding immediately to be used to support their initial EHR planning activities. For example, initial planning regarding the design and development of the anticipated SMHP may be eligible for the 90 percent FFP as an expense related to the administration of the Medicaid incentive payments under section 1903(a)(3)(F) of the Act and, more broadly, for promoting health information exchange. Our review process would ensure that States are complying with requirements in the Act, and that they demonstrate to the "satisfaction of the Secretary" that they are using the funds in the manner anticipated by the law; for example, because of our oversight responsibilities simply proposing activities does not ensure the 90 percent FFP. We would review and prior approve all elements of the State's SMHP, and APD documents.

States would be required to submit these advance planning documents in order for us to approve receipt of the 90 percent Federal match. Specifically, prior approval would be required for the HIT PAPD (see also § 495.336). The deliverable resulting from the HIT PAPD would be the SMHP. The SMHP would be reviewed and approved before it is included in an Implementation APD (IAPD) (see also § 495.338). The IAPD also must be prior approved. Until approval is granted States cannot draw down funds. The APD process allows States to update their APD when they anticipate changes in scope, cost, schedule, etc. This allows States to add additional tasks to the contract which they may have not thought of at the time the HIT PAPD was written, as they worked through the original tasks on the original submission. Something as complex as this will most likely result in an "as needed" and "annual" update to the original scope of work.

For purposes of the Medicaid EHR incentive program, we envision two high-level phases in the process of planning and implementing the incentive program, as well as the promoting the adoption of EHR. Phase I would include initial planning, including an assessment of the State EHR environmental landscape, and development of the SMHP. The vehicle for informing us of Phase I activities will be the HIT PAPD. Phase II will

involve further development and full implementation of the SMHP.

Consequently, we would be requiring the HIT IAPD as the vehicle for reporting of Phase II activities. We are also proposing to require a prior approval process, and anticipate that States would work closely with us in developing the HIT PAPD prior to initiating EHR planning activities and prior to submission of the initial HIT PAPD. State collaboration with us prior to initiating submission of these documents would assist States in understanding all of the requirements and would help us understand the State's strategy and plans which would lead to a more effective implementation. In addition, such coordination would facilitate improved understanding of existing State EHR planning and implementation efforts in progress that should be combined with this effort (that is, health information exchange, EHR demonstration, and Medicaid Transformation Grants).

Also, States would be required to obtain prior written approval of funding, planning documents, proposed budgets, project schedules, and certain implementation activities that a State may wish to pursue in support of the Medicaid EHR incentive program to encourage the adoption and use of certified EHR technology in line with the 90 percent FFP available to States. To minimize the burden on States, these prior approval conditions, and the prior approval process, would mirror that presently used in support of acquiring automated data processing equipment and services in conjunction with development and operation of State MMIS, or the State's automated mechanized claims processing and information retrieval system approved by CMS.

In considering the States' strategies for adoption of EHR and health information exchange, current efforts such as the State MMIS or automated mechanized claims processing and information retrieval system, contain a great deal of claims data and other Medicaid programmatic information. The State MMIS can be of significant value in analyzing the State's current position and moving the State forward to using certified EHR technology to promote health information exchange, enhance quality, and improve health care outcomes. Additionally, the MITA framework provides a conceptual model for building capacity in Medicaid EHR and health information exchange.

We are also proposing that State Medicaid programs must comply with current procurement standards. Specifically, we are including language

in this proposed rule in accordance with the procurement requirements in 45 CFR Part 95 Subpart F to incorporate much of the procurement standards previously contained in 42 CFR Part 74. Inclusion of these procurement requirements maintains the long-standing procurement standards and policies for State information technology contracts, as well as incorporate procurement standards under the authority of section 1902(a)(4) of the Act, specifically for the definition of sole source justification, requiring all procurement transactions to be conducted in a manner to provide, to the maximum extent practical, open and free competition and promote the administration of the Medicaid program in a cost effective manner. This proposed rule also addresses grantee responsibilities, codes of conduct, competition, procurement procedures, and access to records that are specific to the HIT requirements envisioned under the ARRA. Also, under the authority of section 1902(a)(4) of the Act, we are proposing contracting requirements, reporting requirements, systems of records access, software and ownership rights, and rules for charging equipment and cost allocation plans. All of these efforts would work to provide clarity for States when considering planning and implementation activities, and would also ensure that we are providing necessary direction for States in completing their HIT PAPD, HIT IAPD, and SMHP. We are proposing under the authority of 1902(a)(4) of the Act to establish requirements for termination of FFP in the case of States failing to provide access to information relating to any of the requirements of this subpart. Additionally, under section 1903(t)(10) of the Act, we are required to monitor and report on the progress of implementation of the EHR provisions. These proposed provisions would contribute to the overall effort in monitoring implementation efforts and provide relevant information to Congress and the public at large.

Consistent with our oversight responsibilities, we are also proposing to provide a framework for attestations. Specifically, in section II.D.7 of this proposed rule, we discuss that we would require that providers attest to their efforts to adopt, implement or upgrade certified EHR technology, and attest to their meaningful use of such technology. In this section, we discuss our proposal that State Medicaid agencies would attest, as outlined in section 1903(t)(6)(A)(i) of the Act, that States would make Medicaid incentive payments to a Medicaid EP or eligible

hospital directly (or to an employer or facility to which such Medicaid EP or eligible hospital has assigned their Medicaid incentive payments) without any deduction or rebate, and that States would attest that payments to an entity promoting the adoption of certified EHR technology, as designated by the State, would only be made if participation in such a payment arrangement is voluntary for the Medicaid EP involved, and if such entity does not retain more than 5 percent of such assigned Medicaid incentive payments for costs not related to such technology. States would be required to attest that the entire incentive payment has been forwarded to the eligible Medicaid provider, and that no eligible Medicaid provider is required to return any portion of the incentive payment to the State Medicaid agency. We expect States to consider utilizing all existing fiscal relationships as intermediaries for disbursing the incentives. Since many States never pay the provider directly, but rather pay a managed care plan, which then pays the provider, the State may have no existing relationship and decide to contract with the managed care plan to pass this incentive to the EP. States must establish a process to ensure that any existing fiscal relationships with providers to disburse the Medicaid incentive payments through Medicaid managed care plans does not result in payments that exceed 105 percent of the capitation rate, in order to comply with the Medicaid managed care incentive payment rules at § 438.6(c)(5)(iii) and a methodology for verifying such information.

Additionally, we are proposing that termination of funding approved under this proposed Part 495 subpart D or disallowance of FFP may result if the State fails to meet the requirements and undertakings of the approved PAPD, SMHP, and IAPD, or fails to provide access to the required information.

Since section 4201 of the HITECH Act amends section 1903(a)(3) of the Act to provide for 90 percent FFP for costs associated with certain administrative activities performed by a State, we also are proposing to allow for claiming of such reasonable costs incurred on or after February 18, 2009, prior to publication of the final rule. Specifically, if a State can show that it has begun the initial planning stages of moving the State in the direction of meaningful use of certified EHR technology through such activities as training efforts, staff support, or contracting with a vendor, we may allow for retroactive FFP back to the date in which these efforts began, but not before February 18, 2009.

9. Financial Oversight, Program Integrity and Provider Appeals

Pursuant to section 1903(t)(9) of the Act, which requires States to conduct adequate oversight of the incentive program, and in order to ensure that ARRA funds are expended wisely and in a manner that impedes waste, fraud or abuse of Federal taxpayer money, at § 495.366, we propose requirements for States' financial oversight and monitoring of expenditures. Additionally, we are proposing at § 495.368 to provide State requirements for combating fraud and abuse.

Specifically, States would be responsible for estimating the expenditures for the Medicaid EHR incentive program on the State's quarterly budget estimate reports. These reports are used as the basis for Medicaid quarterly grant awards that would be advanced to the State for the Medicaid EHR incentive program. The State submits this Form electronically to CMS via the Medicaid and State CHIP Budget and Expenditure System (MBES/CBES). At the end of the quarter, the State would be responsible for submitting expenditures to us via the MBES Form CMS-64. The Form CMS-64 is the accounting statement that the State Agency, in accordance with 42 CFR 430.30(c), submits each quarter under Title XIX of the Act. The form is used to reconcile the Medicaid funding advanced to the State for the quarter made on the basis of the CMS-37, with actual expenditures for the quarter. It accounts for any overpayments, underpayments, refunds received by the State Medicaid agency, and income earned on grant funds. States must assure that requests for reimbursement of FFP comply with all sections of this new part and that the amounts reported on the Form CMS-64 and its attachments represent actual expenditures for which all supporting documentation, in readily reviewable form, has been compiled and which is available at the time the claim for reimbursement of provider payment incentives and administration funding is filed.

We would assure that State expenditures claimed for Federal matching under the Medicaid program are programmatically reasonable, allowable, and allocable in accordance with existing Federal laws, regulations, and policy guidance. CMS' Regional Office financial and auditing specialists will be responsible for monitoring State funding issues including the funding related to these Medicaid EHR payment incentives. Funding specialists would also review the flow of funds to determine that State funds are from

allowable sources and to insure that Medicaid payment incentives would be paid without reduction or rebate. Additionally, funding specialists would ensure that no other sources of funding are used to make Medicaid EHR payment incentives to providers other than State and local government funds. States would be responsible for establishing policies, computer systems, edits to process Medicaid EHR incentive payments; and for conducting analyses of providers' patterns of practice (data-mining) and taking other reasonable steps to ensure that no duplicate or otherwise improper EHR incentive payments have been made. States will be responsible for ensuring that provider information, including but not limited to, attestations, survey, and any information added to CMS' single provider election repository indicates that any falsification of documentation or concealment of material facts may be prosecuted under Federal and State laws. States would be responsible for recovering and returning to CMS FFP for any HIT incentive payments that are discovered to be improper. State Agencies must have information processing systems, including a MMIS—the automated mechanized claims processing and information retrieval system, to process Medicaid EHR incentive payments. MMIS systems can also help to manage information for program administration and audit purposes.

States must assure that any requests for reimbursement of the 90 percent Federal match for administration of the program are being requested only because the State has used the funds for purposes related to administering payments to qualified Medicaid providers for certified EHR technology, including for tracking of meaningful use of such technology, is conducting adequate oversight of the program including routine tracking of meaningful use attestations and reporting mechanisms; and is pursuing initiatives to encourage the adoption of certified EHR technology to promote health care quality and the exchange of health care information because of such technology. Any initiatives for health information exchange must be consistent with Federal laws and regulations governing the exchange.

We would monitor State Agency compliance through systems performance reviews, on-site reviews, and audits of the APD process.

As a result of the authority extended to the Secretary under section 1902(a)(4) of the Act requiring the effective and efficient administration of the State plan, as well as section 1903(t)(9) of the

Act, requiring that a State demonstrate to the satisfaction of the Secretary that it is conducting adequate oversight of the program, we are also proposing to establish § 495.370, Provider Appeals. This proposed section would specify that Medicaid providers who believe that they have been denied an incentive payment or have received an incorrect payment amount under this part because of incorrect determinations of eligibility, including, but not limited to, measuring patient volume; demonstrating meaningful use of, or the efforts to adopt, implement, or upgrade to, certified EHR technology; whether the professional is hospital-based; whether the professional is practicing predominantly in an FQHC or RHC; whether the hospital qualifies as an acute care or children's hospital; or whether the provider is already participating in the Medicare incentive program and therefore ineligible duplicate Medicaid incentive program payments can appeal the decision using current Federal processes established at 42 CFR 447.253(e).

III. Information Collection Requirements

Under the Paperwork Reduction Act of 1995, CMS is 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 CMS solicit comment on the following issues:

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

The following is a discussion of the requirements we believe are subject to PRA and collection of information requirements as a result of this proposed rule. The projected numbers of EPs and eligible hospitals, MA organizations, MA EPs and MA-affiliated hospitals are based on the numbers used in the Impact Analysis Assumptions as well as in Table 45 in the Regulatory Impact Analysis section.

A. ICRs Regarding Demonstration of Meaningful Use Criteria (§ 495.8)

In § 495.8(a)(1), we propose that to demonstrate meaningful use for CY 2011, an EP must attest, through a secure mechanism in a specified manner, to the following: (1) During the EHR reporting period, the EP used certified EHR technology and specify the technology used; and (2) during the EHR reporting period, the EP satisfied each of the applicable objectives and associated measures under § 495.6 (including quality measures). The EP must specify the EHR reporting period and provide the result of each applicable measure for all patients seen during the EHR reporting period for which a selected measure is applicable. We estimate that the certified EHR technology adopted by the EP will capture many of the Meaningful Use objectives and associated measures and generate automated numerator and denominator information, where required, or automated summary reports. Therefore, for these objectives and associated measures (Set A), we estimate that it would take no more than 0.5 hours for an EP to attest to them collectively as the EHR would be able to gather all of the information necessary for the provider. For objectives and associated measures requiring a numerator and denominator we limit to actions taken in the presence of certified EHR technology. We do not anticipate that an EP or eligible hospital will maintain two record keeping systems when certified EHR technology is present. Therefore, we assume that all patient records that would be in the denominator would be kept using certified EHR technology. Because generating this automated information requires the purchase of a certified EHR with the requisite technical functionality, reporting these measures will incur significant capital costs.

However, there are still some Meaningful Use objectives and associated measures (Set B) where reporting may require EPs to manually gather the information necessary to report numerators and denominators or to take any other additional steps before attesting that the objective has been met, we have estimated that it would take 1 hour for the EP to gather that information and report the result. For example, the measure "At least 80 percent of all patients who request an electronic copy of their health information are provided it within 48 hours" requires EPs to not only provide that information (a third-party disclosure) but also attest to the provision of that information for 80

percent of all patients who request that information. Another example is the CPOE measure. The numerator for the CPOE measure could be generated by the certified EHR technology adopted by the EP, as all orders entered through CPOE could be tracked. However, the denominator for this measure could require EPs to manually track the number of orders entered through paper-based processes. Alternatively, EPs may choose to purchase EHRs equipped with additional functionality

to enable the tracking of all orders, whether entered using CPOE or otherwise, in which case reporting burden may be less than an hour but the capital costs will be higher. We invite comments on what the incremental costs of such additional functionality may be and what the reporting burden using EHRs equipped with this functionality might be.

Table 33 below lists those objectives and associated measures which we estimate will require 0.5 hours to fulfill

(“Set A”) and those objectives and associated measures which we estimate will take 1 hour each (“Set B”). We welcome comments on our burden estimates for each particular measure, as well as what the incremental capital costs attributable to each measure might be. Estimates of total capital costs at the bottom of Table 33 are derived from the estimates used in the “Industry Costs” section in Section V.G.4.

BILLING CODE 4120-01-P

TABLE 33: Burden and Capital Costs associated with Meaningful Use Objectives and Associated Measures

	Stage 1 Objectives		Stage 1 Measures and Reporting Requirements	Burden Estimate per Respondent	Capital Cost (not net of EHR incentive payments)
	Eligible Professionals	Hospitals			
Set A	Implement drug-drug, drug-allergy, drug-formulary checks	Implement drug-drug, drug-allergy, drug-formulary checks	The EP/eligible hospital has enabled this functionality Reporting requirement: Attestation of implementation	The burden associated with this measures is included in the 0.5 hour attestation burden estimate	TBD – costs associated with medication error e-prescribing functions
	Maintain an up-to-date problem list of current and active diagnoses based on ICD-9-CM or SNOMED CT [®]	Maintain an up-to-date problem list of current and active diagnoses based on ICD-9-CM or SNOMED CT [®]	At least 80% of all unique patients seen by the EP or admitted to the eligible hospital have at least one entry or an indication of none recorded as structured data Reporting requirement: numerator and denominator data	The burden associated with this measures is included in the 0.5 hour attestation burden estimate	TBD – cost of functionality that can incorporate diagnoses in coded format

	Stage 1 Objectives		Stage 1 Measures and Reporting Requirements	Burden Estimate per Respondent	Capital Cost (not net of EHR incentive payments)
	Eligible Professionals	Hospitals			
	Maintain active medication list	Maintain active medication list	<p>At least 80% of all unique patients seen by the EP or admitted to the eligible hospital have at least one entry (or an indication of "none" if the patient is not currently prescribed any medication) recorded as structured data</p> <p>Reporting requirement: numerator and denominator data</p>	The burden associated with this measures is included in the 0.5 hour attestation burden estimate	TBD – cost of functionality that can incorporate medication information in coded format
	Maintain active medication allergy list	Maintain active medication allergy list	<p>At least 80% of all unique patients seen, by the EP or admitted to the eligible hospital have at least one entry or (an indication of "none" if the patient has no medication allergies) recorded as structured data</p> <p>Reporting requirement: numerator and denominator data</p>	The burden associated with this measures is included in the 0.5 hour attestation burden estimate	TBD – cost of functionality that can incorporate medication allergy information in coded format

	Stage 1 Objectives		Stage 1 Measures and Reporting Requirements	Burden Estimate per Respondent	Capital Cost (not net of EHR incentive payments)
	Eligible Professionals	Hospitals			
	Record demographics ○ preferred language ○ insurance type ○ gender ○ race ○ ethnicity ○ date of birth	Record demographics ○ preferred language ○ insurance type ○ gender ○ race ○ ethnicity ○ date of birth ○ date and cause of death in the event of mortality	At least 80% of all unique patients seen by the EP or admitted to the eligible hospital have demographics recorded as structured data Reporting requirement: numerator and denominator data	The burden associated with this measures is included in the 0.5 hour attestation burden estimate	TBD – cost of functionality that can incorporate this information in coded format
	Record and chart changes in vital signs: ○ height ○ weight ○ blood pressure ○ Calculate and display: BMI ○ Plot and display growth charts for children 2-20 years, including BMI.	Record and chart changes in vital signs: ○ height ○ weight ○ blood pressure ○ Calculate and display: BMI ○ Plot and display growth charts for children 2-20 years, including BMI.	For at least 80% of all unique patients age 2 and over seen by the EP or admitted to eligible hospital, record blood pressure and BMI; additionally plot growth chart for children age 2-20 Reporting requirement: numerator and denominator data	The burden associated with this measures is included in the 0.5 hour attestation burden estimate	TBD – cost of functionality that can incorporate this information in coded format
	Record smoking status for patients 13 years old or older	Record smoking status for patients 13 years old or older	At least 80% of all unique patients 13 years old or older seen by the EP or admitted to the eligible hospital have "smoking status" recorded Reporting requirement: numerator and denominator data	The burden associated with this measures is included in the 0.5 hour attestation burden estimate	TBD – cost of functionality that can incorporate this information in coded format

	Stage 1 Objectives		Stage 1 Measures and Reporting Requirements	Burden Estimate per Respondent	Capital Cost (not net of EHR incentive payments)
	Eligible Professionals	Hospitals			
	Report ambulatory quality measures to CMS or the States	Report hospital quality measures to CMS or the States	For 2011, provide aggregate numerator and denominator through attestation as discussed in section II(A)(3) of this proposed rule For 2012, electronically submit the measures as discussed in section II(A)(3) of this proposed rule	For 2011, the burden associated with these measures is estimated to be (an additional) 0.5 hour to select the measures and to attest to the numerator and denominator for each. For 2012, the burden is estimated to be (an additional) 0.5 hour to e report and send the electronic submission.	TBD – Cost of the functionality to capture and report on quality measures
	Send reminders to patients per patient preference for preventive/ follow up care		Reminder sent to at least 50% of all unique patients seen by the EP that are age 50 or over Reporting requirement: numerator and denominator data	The burden associated with this measures is included in the 0.5 hour attestation burden estimate	TBD – cost of having functionality to send reminders to patients
	Implement clinical 5 decision support rules relevant to specialty or high clinical priority, including diagnostic test ordering, along with the ability to track compliance with those rules	Implement 5 clinical decision support rules related to a high priority hospital condition, including diagnostic test ordering, along with the ability to track compliance with those rules	Implement 5 clinical decision support rules relevant to the clinical quality metrics the EP/Eligible Hospital is responsible for as described further in section II(A)(3). Reporting requirement: attest to the implementation	The burden associated with this measures is included in the 0.5 hour attestation burden estimate	TBD – costs associated with clinical decision support functionality

	Stage 1 Objectives		Stage 1 Measures and Reporting Requirements	Burden Estimate per Respondent	Capital Cost (not net of EHR incentive payments)
	Eligible Professionals	Hospitals			
	Check insurance eligibility electronically from public and private payers	Check insurance eligibility electronically from public and private payers	Insurance eligibility checked electronically for at least 80% of all unique patients seen by the EP or admitted to the eligible hospital Reporting requirement: numerator and denominator data	The burden associated with this measures is included in the 0.5 hour attestation burden estimate	TBD – cost administrative simplification functionality
	Submit claims electronically to public and private payers.	Submit claims electronically to public and private payers.	At least 80% of all claims filed electronically by the EP or the eligible hospital Reporting requirement: numerator and denominator data	The burden associated with this measures is included in the 0.5 hour attestation burden estimate	TBD – costs associated with administrative simplification functionality
	Provide clinical summaries for patients for each office visit		Clinical summaries provided for at least 80% of all office visits Reporting requirement: numerator and denominator data	The burden associated with this measures is included in the 0.5 hour attestation burden estimate	TBD – cost an EHR system capable of storing this information and transmitting it to patients

	Stage 1 Objectives		Stage 1 Measures and Reporting Requirements	Burden Estimate per Respondent	Capital Cost (not net of EHR incentive payments)
	Eligible Professionals	Hospitals			
	Capability to exchange key clinical information (for example, problem list, medication list, allergies, diagnostic test results), among providers of care and patient authorized entities electronically	Capability to exchange key clinical information (for example, discharge summary, procedures, problem list, medication list, allergies, diagnostic test results), among providers of care and patient authorized entities electronically	Performed at least one test of certified EHR technology's capacity to electronically exchange key clinical information Reporting requirement: attestation that at least one test was performed	The burden associated with this measures is included in the 0.5 hour attestation burden estimate	TBD – cost an EHR system capable of storing this information and transmitting it to providers and patient authorized entities
	Capability to submit electronic data to immunization registries and actual submission where required and accepted	Capability to submit electronic data to immunization registries and actual submission where required and accepted	Performed at least one test of certified EHR technology's capacity to submit electronic data to immunization registries Reporting requirement: attestation that at least one test was performed	The burden associated with this measures is included in the 0.5 hour attestation burden estimate	TBD – costs associated with functionality that can capture immunization information and submit that information to immunization registries

	Stage 1 Objectives		Stage 1 Measures and Reporting Requirements	Burden Estimate per Respondent	Capital Cost (not net of EHR incentive payments)
	Eligible Professionals	Hospitals			
		Capability to provide electronic submission of reportable lab results (as required by state or local law) to public health agencies and actual submission where it can be received	<p>Performed at least one test of the EHR system's capacity to provide electronic submission of reportable lab results to public health agencies (unless none of the public health agencies to which eligible hospital submits such information have the capacity to receive the information electronically)</p> <p>Reporting requirement: attestation that at least one test was performed or that no public agencies have the capacity to receive</p>	The burden associated with this measures is included in the 0.5 hour attestation burden estimate	TBD – costs associated with functionality that can capture lab results information and submit that information to public health agencies

	Stage 1 Objectives		Stage 1 Measures and Reporting Requirements	Burden Estimate per Respondent	Capital Cost (not net of EHR incentive payments)
	Eligible Professionals	Hospitals			
	Capability to provide electronic syndromic surveillance data to public health agencies and actual transmission according to applicable law and practice	Capability to provide electronic syndromic surveillance data to public health agencies and actual transmission according to applicable law and practice	<p>Performed at least one test of certified EHR technology's capacity to provide electronic syndromic surveillance data to public health agencies (unless none of the public health agencies to which an EP or eligible hospital submits such information have the capacity to receive the information electronically)</p> <p>Reporting requirement: attestation that at least one test was performed or that no public agencies have the capacity to receive</p>	The burden associated with this measures is included in the 0.5 hour attestation burden estimate	TBD – costs associated with functionality that can capture syndromic surveillance data and submit that information to public health agencies
	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	<p>Conduct or review a security risk analysis per 45 CFR 164.308 (a)(1) and implement security updates as necessary</p> <p>Reporting requirement: attestation that a risk analysis was conducted or reviewed</p>	The burden associated with this measures is included in the 0.5 hour attestation burden estimate	N/A as conducting or reviewing a security risk analysis does not necessarily hinge on the purchase of an EHR or particular EHR functionalities

	Stage 1 Objectives		Stage 1 Measures and Reporting Requirements	Burden Estimate per Respondent	Capital Cost (not net of EHR incentive payments)
	Eligible Professionals	Hospitals			
Total Burden and Incremental Capital Cost for Set A Measures				0.5 hours + 0.5 hour for quality measure attestation/reporting	TBD – some increment of the total capital costs
SET B	Use CPOE	Use of CPOE for orders (any type) directly entered by authorizing provider (for example, MD, DO, RN, PA, NP)	For EPs, CPOE is used for at least 80% of all orders For eligible hospitals, CPOE is used for 10% of all orders Reporting requirement: numerator and denominator data	1 hour to manually derive the denominator (unless EHR is equipped with extra functionality to generate numerator and denominator data automatically) and attest to the measure. Total: 1 hour	TBD – cost of a CPOE module; additionally, the cost of extra functionality to generate numerator and denominator information automatically
	Generate and transmit permissible prescriptions electronically (eRx)		At least 75% of all permissible prescriptions written by the EP are transmitted electronically using certified EHR technology Reporting requirement: numerator and denominator data	1 hour to manually derive the denominator (unless EHR is equipped with extra functionality to generate numerator and denominator data automatically) and attest to the measure. Total: 1.0 hour	TBD – cost of an e-prescribing system; additionally, the cost of extra functionality to generate numerator and denominator information automatically
	Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, and outreach	Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, and outreach	Generate at least one report listing patients of the EP or eligible hospital with a specific condition. Reporting requirement: attest that at least one report was generated	1 hour to generate the report and attest to the measure Total: 1.0 hour	TBD – cost of having an EHR registry function

	Stage 1 Objectives		Stage 1 Measures and Reporting Requirements	Burden Estimate per Respondent	Capital Cost (not net of EHR incentive payments)
	Eligible Professionals	Hospitals			
	Incorporate clinical lab-test results into EHR as structured data	Incorporate clinical lab-test results into EHR as structured data	At least 50% of all clinical lab tests ordered whose results are in a positive/negative or numerical format are incorporated in certified EHR technology as structured data Reporting requirement: numerator and denominator data	1 hour to manually derive the denominator (unless EHR is equipped with extra functionality to generate numerator and denominator data automatically) and attest to the measure. Total: 1.0 hour	TBD – cost of extra functionality to generate numerator and denominator information automatically
	Provide patients with an electronic copy of their health information (including diagnostic test results, problem list, medication lists, allergies), upon request	Provide patients with an electronic copy of their health information (including diagnostic test results, problem list, medication lists, allergies, discharge summary, procedures), upon request	At least 80% of all patients who request an electronic copy of their health information are provided it within 48 hours Reporting requirement: numerator and denominator data	1 hour to account for the burden associated with determining the denominator and attest to the measure Total: 1.0 hour	TBD – cost an EHR system capable of storing this information and transmitting it to patients
		Provide patients with an electronic copy of their discharge instructions and procedures at time of discharge, upon request	At least 80% of all patients who are discharged from an eligible hospital and who request an electronic copy of their discharge instructions and procedures are provided it Reporting requirement: numerator and denominator data	1 hour to account for the burden associated with determining the denominator and attest to the measure Total: 1.0 hour	TBD – cost an EHR system capable of storing this information and transmitting it to patients

	Stage 1 Objectives		Stage 1 Measures and Reporting Requirements	Burden Estimate per Respondent	Capital Cost (not net of EHR incentive payments)
	Eligible Professionals	Hospitals			
	Provide patients with timely electronic access to their health information (including lab results, problem list, medication lists, allergies) within 96 hours of the information being available to the EP		At least 10% of all unique patients seen by the EP are provided timely electronic access to their health information Reporting requirement: numerator and denominator data	1 hour to account for the burden associated determining whether information is timely and attest to the measure Total: 1.0 hour	TBD – cost an EHR system capable of storing this information and making it continuously available to patients
	Perform medication reconciliation at relevant encounters and each transition of care	Perform medication reconciliation at relevant encounters and each transition of care	Perform medication reconciliation for at least 80% of relevant encounters and transitions of care Reporting requirement: numerator and denominator data	1 hour to account for the burden associated with determining the denominator of all relevant encounters and transitions of care, and attest to the measure Total: 1.0 hour	TBD – cost an e-prescribing system capable of medication reconciliation
	Provide summary care record for each transition of care and referral	Provide summary care record for each transition of care and referral	Provide summary of record for at least 80% of transitions of care and referrals Reporting requirement: numerator and denominator data	1 hour to account for the burden associated with determining the denominator of all relevant encounters and transitions of care and attest to the measure Total: 1.0 hour	TBD – cost an EHR system capable of storing this information and transmitting it to patients
Estimated Total Burden and Incremental Capital Cost per Respondent for Set B measures				7.0 hours for eligible hospitals 8.0 hours for EPs	TBD – some increment of the total capital costs

	Stage 1 Objectives		Stage 1 Measures and Reporting Requirements	Burden Estimate per Respondent	Capital Cost (not net of EHR incentive payments)
	Eligible Professionals	Hospitals			
Estimated Total Burden and Total Capital Cost per Respondent for attestation to EHR technology, Set A Set B measures, and attestation and reporting of quality measures				8 hours for hospitals 9 hours for EPs	Hospitals: \$5 million to install; \$1 million annual maintenance/training costs EPs: \$54,000 to install; \$10,000 annual maintenance/training costs

*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 additional burden associated with the conduct or review of such analyses.

BILLING CODE 4120-01-C

First, we will discuss the burden associated with EP attestation to EHR technology and Meaningful Use Set A objectives/measures, and ambulatory quality measures. We estimate that it will take no more than 0.5 hour for an EP to attest that during the EHR reporting period, he or she used certified EHR technology and specify the technology, and satisfied each of the applicable Meaningful Use Set A objectives/measures. We also estimate that it will take an EP an additional 0.5 hour to select and attest to the ambulatory quality measures for CY 2011. The total burden hours for an EP to attest to the above is one hour. We estimate that there are about 442,600 non-hospital-based Medicare and Medicaid EPs (323,500 Medicare EPs, 80,900 dual Medicare/Medicaid EPs and 38,200 Medicaid-eligible-only EPs) who may attest to the above (after registration) in CY 2011 to receive an EHR incentive payment. We estimate the burden for the 28,000 MA EPs in the MAO burden estimate section. The total estimated annual attestation burden hours for EHR technology, Meaningful Use Set A objectives/measures, and ambulatory quality measures are 442,600 for all EPs (442,600 EPs × 1 hour). The cost burden for an EP to attest to the above information is \$79.33 (1 hour × \$79.33 (mean hourly rate for physicians based on the May 2008 Bureau of Labor Statistics)). The total estimated annual cost burden for all EPs to attest to EHR technology, Meaningful Use Set A objectives/measures, and ambulatory quality measures is \$35,111,458 (442,600 EPs × \$79.33). We invite public comments on the estimated percentages and the numbers of (registered) EPs that will attest to the

above in CY 2011 because such information would help us determine more accurately the burden on the EPs.

Next, we discuss the burden for EPs to gather information and attest to Meaningful Use Set B objectives/measures. We estimate that it takes about 8 hours for each EP to comply with this requirement. As stated, we estimate that there are about 442,600 non-hospital-based EPs in CY 2011. The total estimated annual attestation burden hours for all EPs for the Meaningful Use Set B objectives and measures included in Table 33 is 3,540,800 (442,600 EPs × 8 hours). The cost burden for an EP to attest to the above information is \$634.64 (8 hours × \$79.33/hour (the mean hourly rate for physicians based on the May 2008 Bureau of Labor Statistics is \$79.33) and \$280,891,664 for EPs as a whole (3,540,800 hours × \$79.33/hour). We invite public comments on the estimated percentages and the numbers of (registered) EPs that will attest to Set B objectives and measures in CY 2011 because such information would help us determine more accurately the burden on the EPs.

To estimate capital costs, we assume a certified EHR will cost roughly \$54,000 as explained in section V.G.4 of this proposed rule. If 442,600 EPs adopt these EHRs, total capital costs prior to incentives would be roughly \$23.9 billion. We also estimate that in 2011, \$200 million of Medicare incentive payments (the midpoint of the low and high estimates in Tables 36 and 37) and \$900 million of Medicaid incentive payments (the midpoint of the low and high estimates in Tables 45 and 46) would be provided to EPs to help offset those costs. Therefore, we estimate that total net capital costs for EPs in 2011

would be \$22.8 billion (\$23.9 billion – \$200 million – \$900 million). These capital costs would decrease over the course of the EHR incentive programs as additional incentives are provided. Therefore, in 2012, the total net capital costs for EPs would be \$20.6 billion (22.8 billion – \$1.6 billion of Medicare incentives – \$650 million of Medicaid incentives). Over the course of 2011 and 2012, the average net capital costs would be \$21.7 billion.

We expect that there will be a steady growth in EPs. We estimate that in 2012, there are about 447,400 non-hospital-based Medicare, and Medicaid EPs (326,900 Medicare EPs, 81,700 dual Medicare/Medicaid EPs and 38,800 Medicaid-eligible-only EPs) who are qualified to receive EHR incentive payment. In § 495.8(a)(2), we propose that to demonstrate meaningful use for CY 2012 and subsequent years, a (registered) EP is required to attest, through a secure mechanism in a specified manner, to the following: (1) During the EHR reporting period, the EP used certified EHR technology and specify the technology used; and (2) during the EHR reporting period, the EP satisfied each of the applicable objectives and associated measures under § 495.6 except § 495.8(d)(3) “Report ambulatory quality measures to CMS or the States (in the case of Medicaid EPs).”

For burden estimate purposes, we believe the burden associated with gathering the information necessary to provide the attestations for the measures in Table 33, as well as the burden associated with providing the actual attestation, will remain unchanged from CY2011. As detailed in Table 33, some measures (Set A) will require a total of

0.5 hours to report while others (Set B) will require 1 hour.

First, we will discuss the burden for an EP to attest that during the reporting period, he or she used certified EHR technology, specify the EHR technology, and he or she satisfied each of the applicable Set A objectives measures in CY 2012. We estimate it will take no more than 0.5 hour for an EP to attest to the above requirements. For burden estimate purposes, we estimate that all 447,400 non-hospital-based Medicare, and Medicaid EPs (326,900 Medicare EPs, 81,700 dual Medicare/Medicaid EPs and 38,800 Medicaid-eligible-only EPs) may attest (after registration) in 2012 to receive an EHR incentive payment. We estimate the burden for the 28,000 MA EPs in the MAO burden estimate section. We estimate it will take an EP 0.5 hour to attest. The total estimated annual attestation burden hours for all EPs are 223,700 (447,400 EPs \times 0.5 hour). The cost burden for an EP to attest to the above information is \$39.67 (0.5 hour \times \$79.33 (mean hourly rate for physicians based on the May 2008 Bureau of Labor Statistics)). The total estimated annual cost burden for all EPs to attest is \$17,746,121 (223,700 hours \times \$79.33). We invite public comments on the estimated percentages and the numbers of registered EPs that will attest to EHR technology used and Meaningful Use Set A objectives/measures in CY 2012 because such information would help us determine more accurately the burden on the EPs.

Next, we will discuss the estimated burden for EP attestation for Meaningful Use Set B objectives/measures. We estimate it will take an EP 8 hours to gather information and attest to the Meaningful Use Set B objectives/measures. We estimated annual attestation burden hours in CY 2012 for all EPs for the Set B objectives and measures included in Table 33 is 3,579,200 (447,400 EPs \times 8 hours). Therefore, the cost burden for an EP to attest to the above information is \$634.64 per EP (8 hours \times \$79.33/hour (mean hourly rate for physicians based on the May 2008 Bureau of Labor Statistics) and \$283,937,936 for EPs as a whole (3,579,200 hours \times \$79.33/hour (mean hourly rate for physicians based on the May 2008 Bureau of Labor Statistics)).

For "Report ambulatory quality measures to CMS or the States" as stated in § 495.8(a)(2), we propose that in CY 2012, EPs must report, clinical quality information in the form and manner specified by CMS, electronically to CMS. We estimate that the reporting/submission of these data to CMS should not take more than 0.5 hour. The total

annual burden hours for all EPs to report and submit the ambulatory quality measures are 223,700 (447,400 EPs \times 0.5 hour). We believe that an EP may assign a medical secretary to submit the specific ambulatory clinical quality measures to CMS or the States. Therefore, the cost burden for an EP to submit these clinical quality measures is \$7.41 (0.5 hour \times \$14.81 (mean hourly rate for medical secretaries based on the May 2008 Bureau of Labor Statistics)). The total annual cost burden for all EPs to report the clinical quality measures is \$3,312,997 (223,700 hours \times \$14.81 (mean hourly rate for medical secretaries based on the May 2008 Bureau of Labor Statistics)).

Similar to the requirements for EPs, we propose in § 495.10(b)(1) that to demonstrate meaningful use for FY 2011, an eligible hospital or CAH must attest, through a secure mechanism in a specified manner, to the following: (1) During the EHR reporting period, the eligible hospital or CAH used certified EHR technology and specify the technology used; and (2) during the EHR reporting period specified by the eligible hospital or CAH, the eligible hospital or CAH satisfied each of the applicable objectives and associated measures under § 495.6 (including quality measures). The eligible hospital or CAH must specify the EHR reporting period and provide the result of each applicable measure for all patients admitted to the eligible hospital during the EHR reporting period for which a selected measure is applicable.

We estimate that the certified EHR technology adopted by the eligible hospital or CAH will capture many of the objectives and associated measures. We estimate that it would take no more than 0.5 hour for an eligible hospital or CAH to attest that during the EHR reporting period, they used EHR technology, specify the technology used, and satisfied each of the applicable Meaningful Use objectives and associated measures listed in Table 33—Set A. Because generating this automated information requires the purchase of a certified EHR with the requisite technical functionality, reporting these measures will incur significant capital costs.

Where reporting may require eligible hospitals or CAHs to manually gather the information necessary to report numerators and denominators or to take any other additional steps before attesting that the objective has been met, we have estimated that it would take 1 hour for an eligible hospital or CAH to gather that information and report the result. These measures are listed in Table 33—Set B. Alternatively, eligible

hospitals or CAHs may choose to purchase EHRs equipped with additional functionality to enable more efficient reporting, in which case reporting burden may be less than an hour but the capital costs will be higher. We invite comments on what the incremental costs of such additional functionality may be and what the reporting burden using EHRs equipped with this functionality might be.

First, we will discuss the burden for eligible hospitals and CAHs to attest to the technology used and the Meaningful Use Set A objectives/measures and hospital quality measures in FY 2011. We estimate that in FY 2011, there are about 5,011 Medicare and Medicaid eligible hospitals and CAHs that may be qualified to receive EHR incentive payment. We estimate that it will take no more than 1 hour for an eligible hospital or CAH to attest (0.5 hour to attest to the EHR technology used and Meaningful Use Set A objectives/measures, and 0.5 hour to attest to the hospital quality measures—a total of 1 hour.) We estimate that there are about 5,011 Medicare and Medicaid hospitals (including 3,620 acute care hospitals, 1,302 critical access hospitals, 78 Medicaid children's hospitals, and 11 Medicaid cancer hospitals). For burden estimate purposes, we estimate that 5,011 Medicare and Medicaid hospitals may attest (after registration) in FY 2011 to receive an EHR incentive payment. The total estimated annual attestation burden hours for all hospitals are 5,011 (5,011 hospitals and CAHs \times 1 hour). We believe that an eligible hospital or CAH may assign an attorney to attest on their behalf. The cost burden for an eligible hospital or CAH to attest to the above information is \$59.98 (1 hour \times \$59.98 (mean hourly rate for attorneys based on the May 2008 Bureau of Labor Statistics)). The total estimated annual cost burden for all eligible hospitals and CAHs to attest is \$300,560 (5,011 \times \$59.98). We invite public comments on the estimated percentages and the numbers of (registered) eligible hospitals and CAHs that will attest in FY 2011 because such information would help us determine more accurately the burden on the hospitals and CAHs. We also invite comments on the type of personnel or staff that would most likely attest on behalf of eligible hospitals and CAHs.

Next, we will discuss the burden for eligible hospitals and CAHs to gather information and attest to Meaningful Use Set B objectives/measures for FY 2011. We estimate that it may take an eligible hospital and CAH 7 hours to comply with this requirement. As stated, we estimate there are about 5,011

eligible hospitals and CAHs that may attest to Meaningful Use Set B objectives/measures. Therefore, the total estimated annual attestation burden hours for all eligible hospitals and CAHs for the Set B objectives and measures included in Table 33 is 35,077 (5,011 hospitals and CAHs \times 7 hours). We estimate that the hospital or CAH may use an attorney to attest on their behalf. Therefore, the cost burden for an eligible hospital or CAH to attest to Meaningful Use Set B objectives/measures is \$419.86 (7 hours \times \$59.98/hour (mean hourly rate for attorneys based on the May 2008 Bureau of Labor Statistics) and \$2,103,918 for eligible hospitals and CAHs as a whole (35,077 hours \times \$59.98/hour (mean hourly rate for attorneys based on the May 2008 Bureau of Labor Statistics)), not including capital costs.

To estimate capital costs, consistent with the sources cited in V.G.4, we assume that achieving meaningful use will require roughly a \$5 million capital investment for the average hospital. If 5,011 hospitals adopt these EHRs, total capital costs prior to incentives would be roughly \$25.1 billion. We also estimate that in 2011, \$2.1 billion of Medicare incentive payments (the midpoint of the low and high estimates in Tables 39 and 40) and \$900 million of Medicaid incentive payments (the midpoint of the low and high estimates in Tables 45 and 46) would be provided to eligible hospitals and CAHs to help offset those costs. Therefore, we estimate that total net capital costs for hospitals in 2011 would be \$22.1 billion (\$25.1 billion – \$2.1 billion – \$900 million). These capital costs would decrease over the course of the EHR incentive programs as additional incentives are provided. Therefore, in 2012, the total net capital costs for hospitals would be \$19 billion (22.1 billion – \$2.2 billion of Medicare incentives – \$900 million of Medicaid incentives). Over the course of 2011 and 2012, the average net capital costs would be \$20.6 billion.

Similar to the requirements for EPs, we propose in § 495.8(b)(2) that to demonstrate meaningful use in FY 2012 and subsequent years, an eligible hospital or CAH must attest, through a secure mechanism in a specified manner, to the following: (1) During the EHR reporting period, the eligible hospital or qualifying CAH used certified EHR technology and specify the technology used; and (2) during the EHR reporting period specified by the eligible hospital or CAH, the eligible hospital or CAH satisfied each of the applicable objectives and associated measures under § 495.6, except

§ 495.6(e)(2). The eligible hospital or CAH must specify the EHR reporting period and provide the result of each applicable measure for all patients admitted to the eligible hospital during the EHR reporting period for which a selected measure is applicable. We estimate that the certified EHR technology adopted by the eligible hospital or CAH will capture many of the objectives and associated measures. Therefore, we estimate that it would take no more than 0.5 hour for an eligible hospital or CAH to attest to the EHR technology used and objectives and associated measures listed in Table 33–Set A. Because generating this automated information requires the purchase of a certified EHR with the requisite technical functionality, reporting these measures will incur significant capital costs. We do not anticipate there is a significant growth in the number of hospitals or CAHs. We estimate that in FY 2012, the total burden attestation burden hours for hospitals and CAHs are 2,506 (5,011 hospitals and CAHs \times 0.5 hour). We estimate that an eligible hospital or CAH may assign an attorney to attest on their behalf. The attestation burden for an eligible hospital or CAH is \$29.99 (0.5 hour \times \$59.98 (mean hourly rate for attorneys based on the May 2008 Bureau of Labor Statistics)). The total cost burden for all hospitals and CAHs to attest to EHR technology used, and Meaningful Use Set A objectives/measures is \$150,310 (2,506 hours \times \$59.98). We also invite comments on the type of personnel or staff that would mostly likely attest on the behalf of eligible hospitals and CAHs.

Where reporting may require eligible hospitals or CAHs to manually gather the information necessary to report numerators and denominators or to take any other additional steps before attesting that the objective has been met, we have estimated that it would take 1 hour for the eligible hospitals or CAHs to gather that information and report the result for each of these measures or a total of 7 hours to comply with this requirement in FY 2012. These measures are listed in Table 33–Set B. Alternatively, eligible hospitals or CAHs may choose to purchase EHRs equipped with additional functionality to enable more efficient reporting, in which case reporting burden may be less than an hour but the capital costs will be higher. We invite comments on what the incremental costs of such additional functionality may be and what the reporting burden using EHRs equipped with this functionality might be.

For burden estimate purposes, we estimate that there are 5,011 Medicare

and Medicaid hospitals and CAHs that may attest to the above requirements in FY 2012. Therefore, the total estimated annual attestation burden hours for all eligible hospitals and CAHs for the Set B objectives and measures included in Table 33 are 35,077 (5,011 hospitals and CAHs \times 7 hours). We estimate that the hospital or CAH may use an attorney to attest on behalf of its organization. Therefore, the cost burden for an eligible hospital or CAH to attest to the above information is \$419.86 (7 hours \times \$59.98/hour (mean hourly rate for attorneys based on the May 2008 Bureau of Labor Statistics)) and \$2,103,918 for eligible hospitals and CAHs as a whole (35,077 hours \times \$59.98/hour (mean hourly rate for attorneys based on the May 2008 Bureau of Labor Statistics)), not including capital costs.

We estimate the capital cost for 2012 is \$20.6 billion which is the same as 2011, which was discussed earlier.

Under § 495.8, for “Report hospital quality measures to CMS or the States”, we propose that in FY 2012, eligible hospitals must report clinical quality measures through electronic submission from certified EHR technology. The reporting of these data to CMS or States should not take more than 0.5 hour. The total annual reporting burden hours for eligible hospitals and CAHs is 2,506 (5,011 hospitals and CAHs \times 0.5 hour). We believe that an eligible hospital or CAH may assign a medical secretary to report/submit the hospital quality measures to CMS or the States. The reporting cost burden for an eligible hospital or CAH is \$7.41 (0.5 hour \times \$14.81 (mean hourly rate for medical secretaries based on the May 2008 Bureau of Labor Statistics)). The total annual reporting cost burden for all eligible hospitals and CAHs is \$37,113 (2,506 hours \times \$14.81 (mean hourly rate for medical secretaries based on the May 2008 Bureau of Labor Statistics)).

B. ICRs Regarding Participation Requirements for EPs, Eligible Hospitals, and CAHs (§ 495.10)

Since the EHR incentive payment program is new, we do not have enough information to estimate the information collection requirements burden beyond the first payment year for an EP, eligible hospital, or CAH for this provision. Furthermore, the EPs, eligible hospitals, and CAHs can enroll any time during the first 5 years; therefore, it is difficult to predict with certainty the burden beyond the first payment year as the burden depends on the number of participants. Therefore, we provide a best estimate of what we believe the burden associated with this provision might be.

Under § 495.10 (a)(b)(c), we propose that in order for an EP, eligible hospital, or CAH to participate in the Medicare or Medicaid EHR incentive program, they must submit, in a manner specified by CMS, the following initial registration information in the first payment year: (1) Name of the EP, eligible hospital or CAH; (2) the National Provider Identifier (NPI); (3) business address and business phone; (4) Taxpayer Identification Number (TIN) to which the EP wants the incentive payment made; and (5) for an eligible hospital and CAH, their CMS Certification Number (CCN) and its TIN. We estimate that the initial burden associated with the above requirements would be the time required to submit the required registration information.

We estimate that in FY 2011, there are 5,011 Medicare and Medicaid eligible hospitals, and CAHs that may be qualified to receive EHR incentive payment. Since we cannot predict how many eligible hospitals, and CAHs will participate in the EHR incentive payment program, we estimate that all 5,011 hospitals may register for the incentive program for burden estimate purposes. We estimate that it would take no more than 0.5 hour for an eligible hospital or CAH to register. We estimate the total annual burden hours for registration will be 2,506 (5,011 hospitals \times 0.5 hour). Once the decision to participate in the incentive program is made, we believe eligible hospitals or CAHs may assign a medical secretary to submit the registration information. The cost burden for an eligible hospital or CAH to register is \$7.41 (0.5 hour \times \$14.81 (mean hourly rate for medical secretaries based on the May 2008 Bureau of Labor Statistics)). We estimate that the total annual cost burden for eligible hospitals and CAHs to register is \$37,106 (5,011 hospitals \times 0.5 hour \times \$14.81) (mean hourly rate for medical secretaries based on the May 2008 Bureau of Labor Statistics)). We invite public comments on the estimated percentages or the number of eligible hospitals and CAHs that will register for the EHR incentive payment program in 2011 and subsequent years. Such information would help us determine more accurately the burden on the eligible hospitals and CAHs.

We estimate that all 442,600 non-hospital-based Medicare, and Medicaid EPs may register in 2011 to receive an EHR incentive payment. We estimate that it would take no more than 0.5 hour to complete the registration. The total estimated annual registration burden hours for all EPs are 221,300 (442,600 EPs \times 0.5 hour) in the first payment year. We cannot predict if an EP will

register himself or herself or assign a medical secretary to do it on his or her behalf. Therefore, we are doing one high end burden estimate for an EP and one low end burden estimate for a medical secretary. The cost burden for an EP who chooses to register in the EHR incentive payment program himself or herself is \$39.67 (0.5 hour \times \$79.33 (mean hourly rate for physicians based on the May 2008 Bureau of Labor Statistics)). The total estimated annual cost burden for all EPs who register for the EHR incentive payment program themselves is \$17,555,729 (221,300 hours \times \$79.33 (mean hourly rate for physicians based on the May 2008 Bureau of Labor Statistics)). Similarly, the cost burden for an EP who chooses to use medical secretary to register on their behalf is \$7.41 (0.5 hour \times \$14.81 (mean hourly rate for medical secretaries based on the May 2008 Bureau of Labor Statistics)). The total estimated annual cost burden for all EPs who choose to use medical secretaries to register on their behalf is \$3,277,453 (221,300 hours \times \$14.81 (mean hourly rate for medical secretaries based on the May 2008 Bureau of Labor Statistics)). We invite comments on whether we should use the higher cost burden estimate (\$17,555,729) or the lower cost burden estimate (\$3,277,453). We only use the average of the two estimates in the tally in Table 34. We invite public comments on the estimated percentages or the numbers of EPs that will register in 2011 and subsequent years and this information would help us determine more accurately the burden on EPs affected by this proposed rule.

In § 495.10(d), we propose that if there are subsequent changes in the initial registration information, the EP is responsible for providing us with updated changes in the manner specified by us. Based on our experience with provider enrollment, we estimate that about 11 percent of the Medicare and Medicaid EPs may need to update their registration information during a one-year period. We estimate that EPs in this 11 percent (447,400 EPs (estimated number of EPs in CY 2012) \times 11 percent = 49,214 EPs) may only have one occasion that requires updating of information in a given year. For each occasion, we estimate that it would take no more than 0.5 hour to notify us of the changes. With that, we estimate that the annual total burden hours for 49,214 EPs to update changes are 24,607 (49,214 EPs \times 0.5 hour). However, we cannot predict if the EP will update the registration information himself or herself or assign a medical secretary to do it. Therefore, we are

doing two burden estimates for an EP and his/her medical secretary. The cost burden for an EP who chooses to update the registration information himself or herself is \$39.67 (0.5 hour \times \$79.33 (mean hourly rate for physicians based on the May 2008 Bureau of Labor Statistics)). The total estimated annual cost burden for all 49,214 EPs to update registration information themselves is \$1,952,073 (49,214 EPs \times 0.5 hour \times \$79.33 (mean hourly rate for physicians based on the May 2008 Bureau of Labor Statistics)). Similarly, the cost burden for the EP who chooses to use a medical secretary to update registration information on their behalf is \$7.41 (0.5 hour \times \$14.81 (mean hourly rate for medical secretaries based on the May 2008 Bureau of Labor Statistics)). The total estimated annual cost burden for 48,686 EPs who choose to use medical secretaries to update registration information on their behalf is \$364,429 (49,214 EPs \times 0.5 hour \times \$14.81 (mean hourly rate for medical secretaries based on the May 2008 Bureau of Labor Statistics)). We only use the average of the two estimates in the tally in Table 34. We invite comments on whether we should use the higher cost burden estimate (\$1,952,073) or the lower cost burden estimate (\$364,429). We also invite public comments on the estimated percentages and the numbers of EPs that will need to submit subsequent registration changes to us over the course of the EHR incentive payment program and such information would help us determine more accurately the burden on the EPs.

Similarly, for hospitals and CAHs, we propose that if there are subsequent changes in the initial registration information, the eligible hospital or CAH is responsible for providing us with updated information in the manner specified by us. Based on our experience with provider enrollment, we estimate that about 8 percent of the Medicare and Medicaid eligible hospitals and CAH (5,011 hospitals and CAHs \times 8 percent = 401 hospitals) may need to update their registration information during a one-year period. We estimate that eligible hospitals in this 8 percent pool may only have 1 occasion that requires updating of registration information in a given year. For each occasion, we estimate that it would take no more than 0.5 hour to notify us of the changes. With that, we estimate that the total annual burden hours for eligible hospitals and CAHs to update CMS of registration changes are 201 (401 hospitals and CAHs \times 0.5 hour). We believe that eligible hospitals or CAHs may assign a medical secretary

to update the registration information. We estimate the total annual cost burden for eligible hospitals and CAHs to update CMS of registration changes is \$2,969 (401 hospitals and CAHs \times 0.5 hour \times \$14.81) (mean hourly rate for medical secretaries based on the May 2008 Bureau of Labor Statistics)). We invite public comments on the estimated percentages and the numbers of eligible hospitals and CAHs that will submit subsequent registration changes to us over the course of the EHR incentive payment program and this information would help us determine more accurately the burden on the eligible hospitals and CAHs.

In § 495.10(e)(1), we propose that for participation in the EHR incentive payment programs, prior to the first payment year, an EP must notify us in a specified manner as to whether he or she elects to participate in the Medicare or Medicaid EHR incentive program. We estimate that in 2011, there are about 80,900 dual Medicare/Medicaid EPs who may make the initial Medicare and Medicaid program selection. The standard full amount of Medicaid incentive payments that an EP could receive is larger than the standard full amount for the Medicare EP incentive payments. Therefore, for burden estimate purposes, we believe that all of the 80,900 dual Medicare/Medicaid EPs may make the Medicaid program selection for burden estimate purposes. We estimate that it would take no more than 0.5 hour to submit the initial Medicare or Medicaid selection notification to us. We cannot predict if the EP will submit the notification to CMS himself or herself or assign a secretary to do it. Therefore, we are doing one high end estimate and one low end burden estimate for an EP and a medical secretary respectively. The total estimated burden hours for all the dual Medicare/Medicaid EPs to notify CMS of program selection are 40,450 (80,900 EPs \times 0.5 hour) in the first payment year. The cost burden for these EPs who notify CMS of Medicare or Medicaid program selection himself or herself is \$39.67 (0.5 hour \times \$79.33 (mean hourly rate for physicians based on the May 2008 Bureau of Labor Statistics)). The total estimated annual cost burden for all dual Medicare/Medicaid EPs to notify CMS of program selection themselves is \$3,208,899 (40,450 hours \times \$79.33). Similarly, the cost burden for an EP who chooses to use medical secretaries to notify CMS of program selection is \$7.41 (0.5 hour \times \$14.81 (mean hourly rate for medical secretaries based on the May 2008 Bureau of Labor Statistics)). The total

estimated annual cost burden for all dual Medicare/Medicaid EPs who use medical secretaries to notify CMS of program selection is \$599,065 (40,450 hours \times \$14.81 (mean hourly rate for medical secretaries based on the May 2008 Bureau of Labor Statistics)). We only use the average of the two estimates in the tally in Table 34. We invite comments on whether we should use the higher cost burden estimate (\$3,208,899) or the lower cost burden estimate (\$599,065). We also invite public comments on the estimated percentages and the number of dual Medicare/Medicaid EPs that will submit initial Medicare or Medicaid program selection in 2011, 2012, 2013, or 2014 and this information would help us determine more accurately the burden on the EPs affected by the proposed rule.

Under § 495.10(e)(2), we propose that EPs may switch from Medicare to Medicaid EHR incentive program or vice versa one time, and only for payment year 2014 or before. Since we have no knowledge of how many EPs will make the subsequent changes in program selection, we assume that all 81,700 (estimated number of dual Medicare/Medicaid EPs for CY 2012) dual Medicare/Medicaid EPs may make subsequent program selection changes for burden estimate purposes. We estimate that it would take no more than 0.5 hour to submit the Medicare/Medicaid selection change to us. We cannot predict if the EP will submit the change to CMS himself or herself or assign a secretary to do it. Therefore, we are doing one high end burden estimate for an EP and one low end estimate for a medical secretary. The total estimated burden hours for all dual Medicare/Medicaid EPs to notify CMS of program changes are 40,850 (81,700 EPs \times 0.5 hour) in a given year. The cost burden for the EP who choose to notify CMS of Medicare/Medicaid program change himself or herself is \$39.67 (0.5 hour \times \$79.33 (mean hourly rate for physicians based on the May 2008 Bureau of Labor Statistics)). The total estimated annual cost burden for all dual Medicare/Medicaid EPs to notify CMS of program changes themselves is \$3,240,630 (40,850 hours \times \$79.33 (mean hourly rate for physicians based on the May 2008 Bureau of Labor Statistics)). Similarly, the cost burden for an EP who chooses to use a medical secretary to notify CMS of program changes is \$7.41 (0.5 hour \times \$14.81 (mean hourly rate for medical secretaries based on the May 2008 Bureau of Labor Statistics)). The total estimated annual cost burden for all dual Medicare/Medicaid EPs who

use medical secretaries to notify CMS of program changes is \$604,989 (40,850 hours \times \$14.81 (mean hourly rate for medical secretaries based on the May 2008 Bureau of Labor Statistics)). We invite comments on whether we should use the higher cost burden estimate (\$3,240,630) or the lower cost burden estimate (\$604,989). We only use the average of the two estimates in the tally in Table 34. We also invite public comments on the estimated percentages and the numbers of dual Medicare/Medicaid EPs that will submit initial Medicare or Medicaid program changes in 2012, 2013, or 2014 and this information would help us determine more accurately the burden on the EPs affected by the proposed rule.

C. ICRs Regarding Identification of Qualifying MA Organizations, MA-EPs and MA-Affiliated Eligible Hospitals (§ 495.202)

Proposed § 495.202(a)(1) states that beginning with bids due in June 2010 (for plan year 2011), MA organizations seeking reimbursement for qualifying MA EPs and qualifying MA-affiliated eligible hospitals under the MA EHR incentive program are required to identify themselves to CMS in a form and manner specified by CMS, as part of submissions of initial bids under section 1854(a)(1)(A) of the Act. The burden associated with this requirement is providing a list of MA EPs and qualifying MA-affiliated eligible hospitals who may potentially seek for EHR incentive payments. However, for EPs, we believe there is no extra burden incur from this requirements as MA organizations can identify the same lists of names of EPs as they used to satisfy the collection requirements for § 495.204(b)(2) and (5). In other words, when identifying amounts of compensation per § 495.204(b)(2) and (5), qualifying MA organizations will be simultaneously identifying EPs under this requirement. For hospitals, we estimate that it may take no more than 0.25 hour for a MA organization to identify their MA-affiliated hospitals to CMS. There are 29 MA-affiliated eligible hospitals and 12 MA organizations or an average of 2.42 eligible hospitals for each MA organization. The total burden hours for all MA organizations to identify their affiliated hospitals to CMS are 3 hours. We believe a MA organization may use a billing clerk to identify the eligible hospital to us. The cost burden for a MA organization is \$3.86 (0.25 hour \times \$15.44 (mean hourly rate for billing clerks based on the May 2008 Bureau of Labor Statistics)). The total cost burden for all MA organizations to identify their eligible

hospitals to us is \$46.32 ($\3.86×12 MA organizations).

We proposed in § 495.202(a)(3) that qualifying MA organizations offering MA plan types other than HMOs are required to attest to the fact that they meet the definition of HMO in 42 U.S.C. 300gg–91(b)(3)-section 2791(b)(3) of the PHS Act. There is minimal burden associated with this requirement as qualifying MA organizations sponsoring MA coordinated care plans, like PPOs, PSOs, and RPPOs, are not expected to employ physicians that meet the definition of MA EP in section 1853(1)(2) of the Act and therefore, we do not expect any to need to attest. Similarly, we do not expect any MA organizations that offer other plan types other than coordinated care plans to request need to attest to their status for similar reasons.

In § 495.202(a)(4), we propose requiring that, beginning with bids due in June 2014 (for plan year 2015), all MA organizations with potentially qualifying MA EPs or potentially qualifying MA-affiliated eligible hospitals under the MA EHR incentive program to identify themselves to CMS in a form and manner specified by CMS, as part of submissions of initial bids under section 1854(a)(1)(A) of the Act. We cannot estimate the collection burden for this requirement as the timeframe goes beyond the scope of the effective date of the proposed information collection period (three years from the effective date of the final rule).

In § 495.202(b)(1), we propose that a qualifying MA organization, as part of its initial bid starting with plan year 2011, must make preliminary identification of potentially qualifying MA EPs and potentially qualifying MA-affiliated eligible hospitals for which the organization is seeking incentive payments. The burden for this requirement is already addressed in § 495.202 (a)(1) and § 495.204(b)(2)(5). In § 495.202(b)(2), we propose that MA-affiliated organizations must provide and attest to the following information on their MA-affiliated EPs and eligible hospitals: (A) Name of the EP or eligible hospital; (B) address of the EP or eligible hospital; and (C) NPI. We believe that it is customary and business practices of an MA organization to keep the information in (A), (B), and (C) on file. The burden for this requirement is the time it takes to attest to CMS that the MA EPs or MA-affiliated eligible hospitals meet the eligibility criteria. We estimate it should not take more than 0.5 hour for a MA organization to comply with this attestation requirement. The total burden hours for

all MA organizations to attest are 6 hours. We believe that MA organizations may use an attorney to attest on their behalf. The cost burden for a MA organization to attest is \$29.99 (0.5 hour \times \$59.98 (mean hourly rate for attorneys based on the May 2008 Bureau of Labor Statistics)). The total cost burden for all MA organizations to attest is \$359.88 ($\29.99×12 MA organizations). We invite comments on the type of personnel who will mostly likely attest on behalf of MA organizations.

Proposed § 495.202(b)(4) states that all qualifying MA organizations, as part of their initial bids in June 2014 for plan year 2015, must identify potentially qualifying MA EPs and potentially qualifying MA-affiliated eligible hospitals. An attestation that each professional or hospital either meets or does not meet the eligibility criteria must be included as part of the identification submission. We cannot estimate the collection burden for this requirement as the timeframe goes beyond the scope of the effective date of the proposed information collection period (3 years from the effective date of the final rule).

D. ICRs Regarding Incentive Payments to Qualifying MA Organizations for MA-EPs and Hospitals (§ 495.204)

Under § 495.204(b)(2), we propose that a qualifying MAO would need to report to CMS within 30 days 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. Since the tracking of salaries or compensation for MA EPs constitutes usual and customary business practices, the only burden associated with this requirement is the time required to submit the aggregated annual amount of revenue received by each qualifying MA EP for enrollees in MA plans of the MA organization. We estimate that there are 12 MA organizations and 28,000 MA EPs, or an average of 2,333 (28,000 EPs/12 MA organizations) MA EPs affiliated with each qualifying MA organization. We believe that it will take a MA organization 40 hours annually to report the required aggregate revenue data for all its salaried MA EPs, given that all the data are readily available. The total estimated annual burden hours for all MA organizations to comply with this requirement is 480 (12 MA organizations \times 40 hours). We believe MA organizations may involve a billing

clerk to report the required data to CMS. We estimate the cost burden for a MA organization to report is \$617.6 (40 hours \times \$15.44 (mean hourly rate for billing clerk based on the May 2008 Bureau of Labor Statistics)). We estimate the total annual cost burden for all MA organizations to comply with this requirement is \$7,411 (12 MA organizations \times \$617.6).

Under § 495.204(b)(4), we propose that for qualifying MA EPs who are compensated on a salaried basis, CMS requires the qualifying MA organization to develop a methodology for estimating the portion of each qualifying MA EP's salary attributable to providing services that would otherwise be covered under Part B to MA plan enrollees of the MA organization. The methodology: (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 salaried qualifying MA EP. We estimate that it may take a MA organization one and a half hour to develop the methodology. We estimate that there are about two MA organizations that may have the need to develop the methodology. The total burden hours for the MA organizations to develop the methodology are 3 hours (1.5 hours \times 2 MA organizations). A MA organization may use an accountant to develop the methodology. The cost burden for a MA organization is \$47.48 (1.5 hours \times \$31.65 (mean hourly rate for accountants based on the May 2008 Bureau of Labor Statistics)). The total cost burden for the MA organizations to develop the methodology is \$94.95 ($\47.48×2 MA organizations).

In § 495.204(b)(5), we propose that for qualifying MA EPs who are not salaried, qualifying MA organizations would need to obtain, and submit to CMS, attestations from such qualifying MA EPs as to the amount of compensation received by such EPs for MA plan enrollees of the MA organization. We estimate that about 10 percent of the MA EPs (28,000 EPs \times 10 percent = 2,800 EPs) are not salaried and that is an average of 233 (2,800 EPs/12 MA organizations = 233 EPs) non-salaried EPs in each MA organization. We estimate that it may take up to 0.25 hour to electronically obtain and compile each attestation into a document for transmission to CMS. The total burden hours for a MA organization are 58.3 (0.25 hour \times 233 EPs). The total estimated burden hours for all MA organizations are 699 (58.3 \times 12 MA organizations). We believe an MA organization may involve a billing clerk to compile and submit the

compensation information from such attestations. We estimate the cost burden for a MA organizations to comply with this requirement is approximately \$899.38 (0.25 hour \times 233 EPs \times \$15.44 (mean hourly rate for billing clerk based on the May 2008 Bureau of Labor Statistics)). We estimate the total annual cost burden for all MA organizations to comply with this requirement is \$10,792.56 (58.3 hours \times 12 organizations \times \$15.44).

E. ICRs Regarding Meaningful User Attestation (§ 495.210)

Under § 495.210(b), we propose requiring qualifying MA organizations to attest within 30 days after the close of a calendar year whether each qualifying MA EP is a meaningful EHR user. We anticipate that the adopted EHR technology will capture the data for determination whether each qualifying MA EP is a meaningful EHR user. The burden associated with this requirement is the time necessary to attest to the required information. We estimate that there are 12 MA organizations and 28,000 MA EPs, or an average of 2,333 MA EPs affiliated with each qualifying MA organization. We believe that it will take a MA organization about 40 hours annually to attest whether each qualifying MA EP is a meaningful user, given that all the data are captured in the certified EHR technology. The total estimated annual burden hours for all MA organizations to comply with this requirement is 480 (12 MA organizations \times 40 hours). We believe MA organizations may involve an attorney to attest on their behalf. We estimate the cost burden for a MA organization to attest is \$2,399 (40 hours \times \$59.98 (mean hourly rate for attorneys based on the May 2008 Bureau of Labor Statistics)). We estimate the total annual cost burden for all MA organizations to comply with attestation for MA EPs is \$28,790 (12 MA organizations \times \$2,399). We invite comments on the type of personnel, who will mostly attest on behalf of MA organizations.

Section 495.204(c)(2) states that to the extent data are available, qualifying MA organizations must receive hospital incentive payments through their affiliated hospitals under the Medicare FFS EHR hospital incentive program, rather than through the MA EHR hospital incentive program. Under § 495.210(c), we proposed that qualifying MA organizations be required to attest within 30 days after the close of a calendar year whether each qualifying MA-affiliated eligible hospital is a meaningful EHR user. As stated in the preamble, the EHR incentive payments for Medicare FFS

and MA-affiliated hospitals are treated the same as all Medicare-certified MA affiliated hospitals and they will attest like other Medicare FFS hospitals. This means that § 495.210(c) only applies to a MA-affiliated hospital that is not Medicare certified and such type of hospitals do not exist currently. We do not expect there to be any MA-affiliated hospitals that will not be covered under the Medicare FFS EHR hospital incentive program because section 1852(a)(1)(A) of the Act requires MA organizations to provide Part A inpatient services solely through providers that meet applicable requirements of the Medicare program. We have already addressed the attestation burden on hospitals, including MA-affiliated hospitals under § 495.10(b)(2)(i)(ii).

F. ICRs Regarding Establishing Patient Volume (§ 495.306)

Proposed § 495.306(a) states that to establish patient volume, a Medicaid provider must annually meet one of the requirements contained in § 495.306(a)(1). Proposed § 495.306(a)(1)(i) states that except as specified in paragraph (a)(1)(ii) of this section, a Medicaid professional must attest that a minimum of 30 percent of their patient encounters over any continuous 90-day period in the most recent calendar year was covered by Medicaid. Proposed § 495.306(a)(1)(ii)(A) states that a pediatrician must attest that a minimum of 20 percent of his or her patient encounters over any continuous 90-day period in the most recent calendar year was covered by Medicaid. Proposed § 495.306(a)(1)(ii)(B) states that a Medicaid professional practicing predominantly in a FQHC or RHC must attest that a minimum of 30 percent of his or her patient encounters over any continuous 90-day period in the most recent calendar year was with needy individuals as defined in § 495.302. Proposed § 495.306(a)(2) states that an acute care hospital must attest that a minimum of 10 percent of all patient encounters over any continuous 90-day period in the most recent calendar year was covered by Medicaid.

The burden associated with the requirements in this section is the time and effort necessary to submit the information to CMS. In each instance, we estimate that it will take no longer than 0.5 hour to submit the necessary information to CMS. For proposed § 495.306(a)(1)(i) through (ii), we estimate that 119,000 entities will submit the required information. Similarly, we estimate the total annual burden to be 59,500 hours in both

§ 495.306(a)(1)(i) and § 495.306(a)(1)(ii). The total labor cost associated with the requirement in § 495.306(a)(1)(i) is \$4,720,135. The total labor cost associated with the requirement in § 495.306(a)(1)(ii) is \$4,720,135. We reached these costs estimates since it will be important for physicians (rather than staff assistants) to establish patient volume at \$79.33 (mean hourly rate for physicians based on the May 2008 Bureau of Labor Statistics)).

The burden associated with the requirements in proposed § 495.306(a)(1)(ii)(B) and § 495.306(a)(2) is the time and effort necessary to submit the information to CMS. In each instance, we estimate that it will take no longer than 0.5 hour to submit the necessary information to CMS. For proposed § 495.306(a)(1)(ii)(B) and § 495.306(a)(2), we estimate that 3,361 entities will submit the required information. Similarly, we estimate the total annual burden to be 1,815.50 hours in both § 495.306(a)(1)(ii)(B) and § 495.306(a)(2). The total labor cost associated with the requirement in § 495.306(a)(1)(ii)(B) is \$144,024. This cost burden is based on the physician establishing patient volume at \$79.33 (mean hourly rate for physicians based on the May 2008 Bureau of Labor Statistics)). The total labor cost associated with the requirement in § 495.306(a)(2) is \$25,617. This cost burden is based on a secretary reporting patient volume on behalf of the acute care hospital at \$14.11 (mean hourly rate for secretaries based on the May 2008 Bureau of Labor Statistics)).

G. ICRs Regarding Process for Payments (§ 495.312)

Proposed § 495.312(b) states that in order to receive a payment under this part, a provider must report the required data under this subpart within the EHR reporting period described in § 495.6. The data required is the information necessary to document that the provider is a meaningful user or an adopter, implementer, or upgrader of certified EHR technology and the data reported to the single provider election repository. The burden associated with this requirement is the time and effort necessary to report the required data to States during the EHR reporting period. This burden is accounted for in our burden discussions for sections A and B of the information collection section, § 495.10 and § 495.12, respectively.

H. ICRs Regarding Activities Required To Receive an Incentive Payment (§ 495.314)

Proposed § 495.314(a)(1) states that in the first payment year, to receive an

incentive payment, the Medicaid EP or eligible hospital must meet one of the following criteria. The Medicaid EP or eligible hospital must demonstrate that during the EHR reporting period for a payment year, it has adopted, implemented, or upgraded certified EHR technology, as defined in § 495.302; or, the Medicaid EP or eligible hospital must demonstrate that during the EHR reporting period for a payment year it is a meaningful user of certified EHR technology as defined in § 495.6.

The burden associated with the requirements in proposed § 495.314(a)(1) is the time and effort necessary for a Medicaid EP or eligible hospital to demonstrate that it meets one of the criteria in § 495.314(a)(1)(i) through (ii). We already accounted for this burden in the earlier discussion of the burden associated with § 495.10.

Proposed § 495.314(a)(2) states that a provider may notify the State of its nonbinding intention to participate in the incentives program prior to having fulfilled all of the eligibility criteria. This requirement constitutes a third-party disclosure. The burden associated with this requirement is the time and effort necessary for a provider to send notification to the State. We estimate that this burden will be the same burden associated with § 495.12 as stated above, since the information necessary to notify the State of the providers non-binding intention to participate in the program could be the same information as submitted by those providers that have committed to participating in the program, that is, the National Provider Identifier, the tax identification number, etc.

Proposed § 495.314(b)(1) states that in the second, third, fourth, fifth, and sixth payment years, to receive an incentive payment, the Medicaid EP or eligible hospital must demonstrate that during the EHR reporting period for the applicable payment year, it is a meaningful user of certified EHR technology, as defined in § 495.6. The burden associated with this requirement is the time and effort necessary for a Medicaid EP or eligible hospital to demonstrate that it is a meaningful user of certified EHR technology. We discussed the burden associated with this requirement in our discussion of the burden associated with § 495.10.

I. ICRs Regarding State Monitoring and Reporting Regarding Activities Required To Receive an Incentive Payment (§ 495.316)

Proposed § 495.316(a) would require States to be responsible for tracking and verifying the activities necessary for a Medicaid EP or eligible hospital to

receive an incentive payment for each payment year, as described in § 495.314. Burden is calculated for each State's process for the administration of the Medicaid incentive payments, including tracking of attestations and oversight, and the process for approving, processing, and making timely payments.

We estimate that there will be approximately 50 States, the District of Columbia, and 5 Territories per year requesting reimbursement for the administration of and paying of Medicaid incentive payments to providers for the meaningful use of electronic health record systems. For States to collect and submit the information required, we estimate it will take 5 hours per State. The estimated annual burden for States associated with the aforementioned submission requirements is 280 hours (56 States-Territories × 5.0 hours/State-Territory). The cost burden was estimated based on an employee contracting with the State Agency. The burden associated with § 495.316 is already in the OMB approval process. We announced the information collection in a **Federal Register** notice that published on September 11, 2009 (74 FR 467330).

J. ICRs Regarding State Responsibilities for Receiving FFP (§ 495.318)

Proposed § 495.318 states that in order to be provided FFP under section 1903(a)(3)(F) of the Act, a State must demonstrate to the satisfaction of the Department, that the State is conducting the activities listed at § 495.318(a) through (c). This burden is the same as that listed above in the burden discussion for § 495.316.

K. ICRs Regarding Prior Approval Conditions (§ 495.324)

Proposed § 495.324(a) would require a State to obtain prior written approval from the Department as specified in paragraph (b) of this section, when the State plans to initiate planning and implementation activities in support of Medicaid provider incentive payments encouraging the adoption and use of certified EHR technology with proposed Federal financial participation (FFP). Specifically, proposed § 495.324(b) states that to receive 90 percent match, each State must receive prior approval for all of the requirements listed in § 495.324(b)(1) through (3).

Proposed § 495.324(c) would require a State to obtain prior written approval from the Department of its justification for a sole source acquisition, when it plans to acquire non-competitively from a nongovernmental source HIT equipment or services, with proposed

FFP under this subpart if the total State and Federal acquisition cost is more than \$100,000. Burden must be calculated for State Medicaid Agencies to submit the planning and implementation documents and the SMHP to CMS including, among other things, an alternative approach to the established timeframe for measuring patient volume, the process for verifying eligibility, annual reports specifying provider adoption, implementation, and/or upgrading of certified EHR technology activities and payments, proposed additional quality measures, and the data supporting the adoption, implementation, or upgrading and meaningful use of certified EHR technology. This burden is the same as that listed above in the burden discussion for § 495.316.

L. ICRs Regarding Termination of Federal Financial Participation (FFP) for Failure To Provide Access to Information (§ 495.330)

Proposed § 495.330(a) states that the Department terminates FFP at any time if the Medicaid agency fails to provide State and Federal representatives with full access to records relating to HIT planning and implementation efforts, and the systems used to interoperate with electronic HIT, including on-site inspection. Proposed § 495.330(b) states that the Department may request such access at any time to determine whether the conditions in this subpart are being met. The burden associated with the requirements in this section is the time and effort necessary to make the information available to the Department upon request so it can monitor compliance. The Department estimates that it will make 1 request per State/Territory per year for information and that it will take each State 5 hours to compile and furnish the information. We estimate that there will be approximately 50 States, the District of Columbia, and 5 Territories per year submitting this information. For States to collect and submit the information required, we estimate it will take 5 hours per State. The estimated annual burden for States associated with the aforementioned submission requirements is 280 hours (56 States-Territories × 5.0 hours/State-Territory).

The annual cost burden for a State employee to provide the above information is \$9,904 (280 hours × \$35.37 (mean hourly rate for a management analyst based on the May 2008 Bureau of Labor Statistics)). We believe that it is possible that a secretary may compile State information and provide the information to the Department. In that case the annual cost

burden for the secretary to provide this information is \$3,951 (280 hours \times \$14.11 (mean hourly rate for secretaries based on the May 2008 Bureau of Labor Statistics)).

M. 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 adopting, implementing, or upgrading and meaningful use of certified EHR technology. This burden is the same as that listed above in the burden discussion for § 495.316.

N. ICRs Regarding Access to Systems and Records (§ 495.346)

Proposed § 495.346 states that the State agency must allow the Department access to all records and systems operated by the State in support of this program, including cost records associated with approved administrative funding and incentive payments to Medicaid providers. State records related to contractors employed for the purpose of assisting with implementation or oversight activities or providing assistance, at such intervals as are deemed necessary by the Department to determine whether the conditions for approval are being met and to determine the efficiency, economy, and effectiveness of the program.

This section imposes both recordkeeping and reporting requirements. The burden associated with this requirement is the time and effort necessary for a State to both maintain records and to make them available to the Department upon request. The Department believes that the burden associated with maintaining the records is exempt under 5 CFR 1320.3(b)(2) as this burden is part of a usual and customary business practice; the time, effort, and financial resources necessary to comply with a collection of information that would be incurred by persons in the normal course of their activities (for example, in compiling and maintaining business records) will be excluded from the "burden" if the agency demonstrates that the reporting, recordkeeping, or disclosure activities

needed to comply are usual and customary.

However, there is burden associated with making the information available to the Department upon request. This burden is described in the burden discussion for § 495.330.

O. ICRs Regarding Procurement Standards (§ 495.348)

Proposed § 495.348(c) states that a grantee must maintain written standards of conduct governing the performance of its employees engaged in the award and administration of contracts. The burden associated with this requirement is the time and effort necessary for a grantee to develop and maintain written standards of conduct. We estimate that it will take each of the 56 grantees 0.5 hour to develop and maintain standards of conduct. The total estimated annual burden is 28 hours (56 grantees \times 0.5 hours). The annual cost burden for a grantee to develop and maintain standards of conduct is \$990 (28 hours \times \$35.37 (mean hourly rate for a management analyst based on the May 2008 Bureau of Labor Statistics)).

Proposed § 495.348(e) would require that all grantees establish written procurement procedures. At a minimum, the standards must provide for the information listed in § 495.348(e)(1) through (13). The burden associated with this requirement is the time and effort necessary for a grantee to develop and maintain written procurement procedures. We estimate that it will take each of the 56 grantees 0.5 hour to develop and maintain written procurement procedures. The total estimated annual burden is 28 hours (56 grantees \times 0.5 hours). The annual cost burden for a grantee to develop and maintain written procurement procedures is \$990 (28 hours \times \$35.37 (mean hourly rate for a management analyst based on the May 2008 Bureau of Labor Statistics)).

Proposed § 495.348(f) imposes a recordkeeping requirements. This section states that a system for contract administration must be maintained to ensure contractor performance with the terms, conditions and specifications of the contract and to ensure adequate and timely follow up on all purchases. The burden associated with this requirement is the time and effort necessary to develop and maintain a system for contract administration. We estimate that it will take each of the 56 grantees 5 hours to develop and maintain a system for contract administration. The total estimated annual burden is 280 hours (56 grantees \times 5 hours). The annual cost burden for a grantee to develop and maintain a system for

contract administration is \$9,904 (280 hours \times \$35.37 (mean hourly rate for a management analyst based on the May 2008 Bureau of Labor Statistics)).

P. ICRs Regarding State Medicaid Agency Attestations (§ 495.350)

Proposed § 495.350 would require States to provide assurances to the Department that amounts received with respect to sums expended that are attributable to payments to a Medicaid provider for the adoption of EHR are paid directly to such provider, or to an employer or facility to which such provider has assigned payments, without any deduction or rebate. The burden associated with this requirement is the time and effort necessary for a State to verify that the sums expended are attributable to payments to a Medicaid provider for the adoption of EHR are paid directly to such provider, or to an employer or facility to which such provider has assigned payments, without any deduction or rebate. Additionally, there is burden associated with submitting an attestation to the Department to that effect. The estimated burden associated with these requirements is 0.5 hour to verify the information and 0.5 hour to submit the attestation to the Department, for a total of 1 hour. We estimate that there will be approximately 50 States, the District of Columbia and 5 Territories per year verifying this information and submitting attestations to the Department. The estimated annual burden for States associated with the aforementioned submission requirements is 56 hours (56 States-Territories \times 1 hours State-Territory). The annual cost burden for a State employee to provide the above information is \$1,981 (56 hours \times \$35.37 (mean hourly rate for a management analyst based on the May 2008 Bureau of Labor Statistics)). We believe that it is possible that a secretary may compile State information and provide the information to the Department. In that case the annual cost burden for the secretary to provide this information is \$790 (56 hours \times \$14.11 (mean hourly rate for secretaries based on the May 2008 Bureau of Labor Statistics)).

Q. ICRs Regarding Reporting Requirements (§ 495.352)

Proposed § 495.352 would require each State to submit to the Department on a quarterly basis a progress report documenting specific implementation and oversight activities performed during the quarter, including progress in implementing the State's approved Medicaid HIT plan. The burden associated with this requirement is the

time and effort necessary for a State to draft and submit quarterly progress reports to the Department. We estimate that there will be approximately 50 States, the District of Columbia, and 5 Territories per year drafting and submitting the quarterly progress reports. For States to collect and submit the information required, we estimate it will take 5 hours per State. The estimated annual burden for States associated with the aforementioned submission requirements is 280 hours (56 States-Territories \times 5 hours/State-Territory).

The annual cost burden for a State employee to provide the above information is \$9,904 (280 hours \times \$35.37 (mean hourly rate for a management analyst based on the May 2008 Bureau of Labor Statistics)). We believe that it is possible that a secretary may compile State information and provide the information to the Department. In that case the annual cost burden for the secretary to provide this information is \$3,951 (280 hours \times \$14.11 (mean hourly rate for secretaries based on the May 2008 Bureau of Labor Statistics)).

R. ICRs Regarding Retroactive Approval of FFP With an Effective Date of February 18, 2009 (§ 495.362)

Proposed § 495.362 states that for administrative activities performed by a State, without obtaining prior approval, which are in support of planning for incentive payments to providers, a State may request consideration of FFP by recorded request in a HIT implementation planning advance planning document or implementation advance planning document update. While this requirement is subject to the PRA, we believe the burden is already covered in the discussion of proposed § 495.332 through § 495.344.

S. ICRs Regarding Financial Oversight and Monitoring Expenditures (§ 495.366)

Proposed § 495.366(a)(2) would require a State to have a process in place to report actual expenditures for the Medicaid EHR payment incentive program using the Medicaid Budget Expenditure System. Since States already have to report Medicaid expenditures to the Medicaid Budget and Expenditure System, there is no need for States to develop and implement a reporting process. However, States will need to estimate and report the expenditures related to the provider incentive payments and the cost of the administration of the

incentive payments. We estimate that it will take each of the 50 States, the District of Columbia and 5 Territories, 5 hours to compile and report this information. The estimated annual burden for States associated with the aforementioned requirements is 280 hours (56 States-Territories \times 5 hours/State-Territory).

The annual cost burden for a State employee to provide the above information is \$9,904 (280 hours \times \$35.37 (mean hourly rate for a management analyst based on the May 2008 Bureau of Labor Statistics)). We believe that it is possible that a secretary may compile State information and provide the information to the Department. In that case the annual cost burden for the secretary to provide this information is \$3,951 (280 hours \times \$14.11 (mean hourly rate for secretaries based on the May 2008 Bureau of Labor Statistics)).

Proposed § 495.366(a)(2) would require a State to have an automated payment and information retrieval mechanized system (Medicaid Management Information System), to make EHR payment incentives, to ensure Medicaid provider eligibility, to ensure the accuracy of payment incentives, and to identify potential improper payments. Since States already have an automated payment and information retrieval system, there is no need to estimate this burden.

Proposed § 495.366(b) lists the information collection requirements associated with provider eligibility as a basis for making payment. States must, subject to § 495.332, collect and verify information on Medicaid providers. This burden is the same as that listed above in the discussion of § 495.316.

Proposed § 495.366(c) discusses information collection requirements pertaining to meaningful use and efforts to adopt, implement, or upgrade to certified electronic health record technology to make payment. Specifically, proposed § 495.366(c)(1) states that subject to § 495.332, the State must annually collect and verify information regarding the efforts to adopt, implement, or upgrade certified EHR technology and the meaningful use of said technology before making any payments to providers. This burden has already been discussed in our burden explanation for § 495.10.

Proposed § 495.366(d)(1) states that subject to paragraph § 495.332, the State must assure that State expenditures are claimed in accordance with, including but not limited to, applicable Federal laws, regulations and policy guidance.

Proposed § 495.366(d)(2) specifies that subject to § 495.332, the State must have a process in place to assure that expenditures for administering the Medicaid EHR incentive payment program will not be claimed at amounts higher than 90 percent of the cost of such administration. Proposed § 495.366(d)(3) states that subject to § 495.332, the State must have a process in place to assure that expenditures for payment of Medicaid EHR incentive payments will not be claimed at amounts higher than 100 percent of the cost of such payments to Medicaid providers. This burden is the same as that listed above in the discussion of § 495.316.

Proposed § 495.366(e) discusses the information collection requirements associated with improper Medicaid electronic health record payment incentives. The burden associated with the requirements listed in proposed § 495.366(e)(1) through (7) is the time and effort necessary to develop processes to provide the necessary assurances discussed in this section. This burden is the same as that listed above in the discussion of § 495.316.

T. ICRs Regarding Appeals Process for a Medicaid Provider Receiving Electronic Health Record Incentive Payments (§ 495.370)

Proposed § 495.370(a) would require states to have a process in place consistent with the requirements established in § 447.253(e) of this chapter for a provider or entity to appeal incentive payments, incentive payment amounts, provider eligibility determinations, and the demonstration of adopting, implementing, or upgrading and meaningful use of certified EHR technology. This burden is the same as that listed above in the discussion of § 495.316.

These numbers are subject to a substantial amount of uncertainty and actual experience may be significantly different. The range of possible experience is greater than under most other rules for the following reason; specifically, this rule provides the option for States to participate in the Medicaid certified electronic health record technology incentive payment program. To the extent that States participate more or less than assumed here (that is, the number of States, EPs and hospitals) the burden associated may be greater than or less than estimated.

BILLING CODE 4120-01-P

TABLE 34: Burden and Cost Estimates Associated with Information Collection Requirements

Reg Section	OMB Control No.	Respondents	Responses	Burden per Response (in hours)	Total Annual Burden (in hours)	Hourly Labor Cost of Reporting (\$)	Total Cost of Reporting (\$)	Total Capital/Maintenance Costs (\$)	Total Costs (\$)
\$495.8 (a)(1)– EHR Technology Used, Set A Objectives/Measures & Quality Measures (EPs) (2011)	0938-New	442,600	442,600	1	442,600	79.33	35,111,458	0	35,111,458
\$495.8 (a)(1)– Set B Objectives/Measures (EPs) (2011)	0938-New	442,600	442,600	8	3,540,800	79.33	280,891,664	21,700,000,000	21,980,891,664
\$495.8(a)(2) - EHR Technology Used & Set A Objectives/Measures (EPs) (2012)	0938-New	447,400	447,400	0.5	223,700	79.33	17,746,121	0	17,746,121
\$495.8 (a)(2)– Set B Objectives/Measures (EPs) (2012)	0938-New	447,400	447,400	8	3,579,200	79.33	283,937,936	4,500,000,000	4,783,937,936
\$495.8 (a)(2)– Ambulatory Quality Measures (EPs) (2012)	0938-New	447,400	447,400	0.5	223,700	14.81	3,312,997	0	3,312,997
\$495.8 (b)(1)– EHR Technology Used, Set A Objectives/Measures & Quality Measures (hospitals/CAHs) (2011)	0938-New	5,011	5,011	1	5,011	59.98	300,560	0	300,560
\$495.8(b)(1) – Set B Objectives/Measures (hospitals/CAHs) (2011)	0938-New	5,011	5,011	7	35,077	59.98	2,103,918	20,600,000,000	20,602,103,918
\$495.8 (b)(2)– 1 EHR Technology Used & Set A Objectives/Measures (hospitals/CAHs) (2012)	0938-New	5,011	5,011	0.5	2,506	59.98	150,310	0	150,310
\$495.8 (b)(2)– Set B Objectives/Measures (hospitals/CAHs) (2012)	0938-New	5,011	5,011	7	35,077	59.98	2,103,918	5,000,000,000	5,002,103,918
\$495.8 (b)(2)– Hospital Quality Measures (hospitals/CAHs) (2012)	0938-New	5,011	5,011	0.5	2,506	14.81	37,113	0	37,113
\$495.10(a) – (c) – high (EPs) (2011)	0938-New	442,600	442,600	0.5	221,300	79.33	17,555,729	0	17,555,729
\$495.10(a) – (c) – low (EPs) (2011)	0938-New	442,600	442,600	0.5	221,300	14.81	3,277,453	0	3,277,453
\$495.10(a) – (c) – average (EPs) (2011)	0938-New	442,600	442,600	0.5	221,300	47.07	10,416,591	0	10,416,591
\$495.10(d) – high (EPs) (2012)	0938-New	49,214	49,214	0.5	24,607	79.33	1,952,0732	0	1,952,0732
\$495.10(d) – low (EPs) (2012)	0938-New	49,214	49,214	0.5	24,607	14.81	364,429	0	364,429
\$495.10(d) – average (EPs) (2012)	0938-New	49,214	49,214	0.5	24,607	47.07	1,158,251	0	1,158,251
\$495.10(e)(1) – high (EPs) (2011)	0938-New	80,900	80,900	0.5	40,450	79.33	3,208,899	0	3,208,899
\$495.10(e)(1) – low (EPs) (2011)	0938-New	80,900	80,900	0.5	40,450	14.81	599,065	0	599,065
\$495.10(e)(1) – average (EPs) (2011)	0938-New	80,900	80,900	0.5	40,450	47.07	1,903,982	0	1,903,982
\$495.10(e)(2) – high (EPs) (2012)	0938-New	81,700	81,700	0.5	40,850	79.33	3,240,630	0	3,240,630
\$495.10(e)(2) – low (EPs) (2012)	0938-New	81,700	81,700	0.5	40,850	14.81	604,989	0	604,989
\$495.10(e)(2) – average (EPs) (2012)	0938-New	81,700	81,700	0.5	40,850	47.07	1,922,810	0	1,922,810

Reg Section	OMB Control No.	Respondents	Responses	Burden per Response (in hours)	Total Annual Burden (in hours)	Hourly Labor Cost of Reporting (\$)	Total Cost of Reporting (\$)	Total Capital/Maintenance Costs (\$)	Total Costs (\$)
§495.10(a) – (b) (hospital) (2011)	0938-New	5,011	5,011	0.5	2,506	14.81	31,706	0	31,706
§495.10(d) – (hospital) (2012)	0938-New	401	401	0.5	201	14.81	2,969	0	2,969
§495.202(a) (2011)	0938-New	12	12	0.25	3	15.44	46	0	46
§495.202(b)(2) (2011)	0938-New	12	12	0.5	6	59.98	360	0	360
§495.204(b)(2) (2011-2012)	0938-New	12	12	40	480	15.44	7,411	0	7,411
§495.204(b)(4) (2011-2012)	0938-New	2	2	1.5	3	31.65	95	0	95
§495.204(b)(5) (2011-2012)	0938-New	12	12	58.3	699	15.44	10,793	0	10,793
§495.210(b) (2011-2012)	0938-New	12	12	40	480	59.98	28,790	0	28,790
§495.306(a)(i) (2011-2012)	0938-New	119,000	119,000	0.5	59,500	79.33	4,720,135	0	4,720,135
§495.306(a)(i)(ii)(A)	0938-New	119,000	119,000	0.5	59,500	79.33	4,720,135	0	4,720,135
§495.306(a)(i)(ii)(B)	0938-New	3,631	3,631	0.5	1,816	79.33	144,024	0	144,024
§495.306(a)(2)	0938-New	3,631	3,631	0.5	1,816	14.11	25,617	0	25,617
§495.316	0938-New	56	56	5	280	100	28,000	0	28,000
§495.330(a) – high	0938-New	56	56	5	280	35.37	9,904	0	9,904
§495.330(a) – low	0938-New	56	56	5	280	14.11	3,951	0	3,951
§495.330(a) – average	0938-New	56	56	5	280	24.74	6,927	0	6,927
§495.348(c)	0938-New	28	28	0.5	28	35.37	990	0	990
§495.348(e)	0938-New	28	28	0.5	28	35.37	990	0	990
§495.348(f)	0938-New	28	28	5	280	35.37	9,904	0	9,904
§495.350--high	0938-New	56	56	1	56	35.37	1,981	0	1,981
§495.350--low	0938-New	56	56	1	56	14.11	790	0	790
§495.350--average	0938-New	56	56	1	56	24.74	1,385	0	1,385
§495.352--high	0938-New	56	56	5	280	35.37	9,904	0	9,904
§495.352--low	0938-New	56	56	5	280	14.11	3,591	0	3,591
§495.352--average	0938-New	56	56	5	280	24.74	6,927	0	6,927
§495.366--high	0938-New	56	56	5	280	35.37	9,904	0	9,904
§495.366--low	0938-New	56	56	5	280	14.11	3,591	0	3,591
§495.366--average	0938-New	56	56	5	280	24.74	6,927	0	6,927
Total 2011*					4,413,559		340,479,335	42,300,000,000	42,640,480,720
Total 2012*					4,258,153		320,091,475	9,500,000,000	9,820,091,475

Note: Where there are low, high, and average estimates listed for the provisions, only the average figures are used for the purpose of burden calculation

* Burden not otherwise designated by year, that is, 2011, 2012, or 2011-2012, is considered to be annual burden and is included in the sum total burden for both 2011 and 2012.

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

Submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule; or submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: CMS Desk Officer, [CMS-0033-P—Meaningful Use] Fax: (202) 395-5806; or E-mail: 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. Overall Impact

We have examined the proposed impacts of this rule as required by Executive Order 12866, the Regulatory Flexibility Act (RFA), section 1102(b) of the Social Security Act regarding rural hospital impacts, the Unfunded Mandates Reform Act, Executive Order 13132 on Federalism, and the Congressional Review Act.

Executive Order 12866 directs 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 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 RIA that to the best of our ability presents the costs and benefits of the proposed rule. We request comments on the analysis provided in this proposed rule.

This proposed rule is one of three coordinated rulemakings undertaken to implement the goals and objectives of the HITECH Act related to the adoption and meaningful use of certified EHR technology. The other two are HHS's interim final rule establishing

certification criteria, standards, and implementation specifications for certification of EHR systems, and the proposed rule on EHR certification programs. Each rule will assess the direct economic effects of the provisions it creates. This proposed rule on Medicare and Medicaid EHR Incentive Programs addresses the impacts related to the actions taken by EPs or eligible hospitals to become meaningful users of certified EHR technology, including purchasing or developing in-house certified EHR technology or EHR technology modules.

A number of factors will affect the adoption of EHR systems and demonstration of meaningful use. Many of these are addressed in this analysis. Readers should understand that these forecasts are subject to substantial uncertainty. Demonstration of meaningful use will depend in part on the final provisions of these three rulemakings, which will depend in turn on comments we now solicit but have not yet received. These three rules deal primarily with standards and requirements for FYs 2011 and 2012, but overall rates of meaningful use of certified EHR technology will depend in part on future rulemakings issued by the HHS.

The HITECH Act provides incentives 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 penalties, 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 massive payment reductions under the sustainable growth rate (SGR) formula for determining Medicare payments. Under the current law, physician payments will be reduced by at least 21 percent beginning in CY 2010. Such reductions would

almost certainly 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 these very large payment reductions. However, the Congress has legislatively avoided physician payment reductions in each of the past 7 years. Behavioral changes resulting from these scheduled physician payment reductions are not included in our estimate and likewise we do not assume any additional behavioral changes from EHR incentive payments for physicians.

All of these factors taken together make it impossible to predict with precision the timing or rates of adoption and ultimately meaningful use. Therefore, we present a range of estimates, which capture how different scenarios will impact overall costs. Our "high" scenario of meaningful use demonstration assumes that roughly a decade from now, nearly 100 percent of hospitals and 70 percent of EPs will be "meaningful users" in the Medicare EHR incentive program. This estimate is based on the substantial economic incentives created by the combined direct and indirect factors affecting providers. We appreciate that in the real world nothing is ever 100 percent, and can even identify factors that would certainly lead providers to forego implementing an EHR. For example, a physician nearing retirement with a low Medicare caseload might well decide to accept the relatively low adverse consequences of declining to demonstrate meaningful use of certified EHR technology. Alternatively, EPs and eligible hospitals and CAHs may choose not to adopt EHRs if the total costs of purchasing certified EHRs and the total costs of complying with this rule are higher than the value of the total EHR incentive payments (and adjustments, if applicable). However, we have no reliable basis for estimating the rate of such "holdouts." To emphasize the uncertainties involved, we have also created a "low" estimate for the demonstration of meaningful use each year. This might best be viewed as a more pessimistic view of the rate at which adoption approaches 100 percent.

Both the high and low estimates are based on current law. That is, we assume that the incentive payments and potential reimbursement reductions set forth in the HITECH Act will remain unchanged. We also assume that the scheduled physician payment

reductions will occur. We appreciate that this assumption reflects the standard practice used in forecasts of government spending (including effects on the private sector) by the Boards of Trustees for the Hospital Insurance and Supplementary Medical Insurance Trust Funds, the Social Security trustees, the Office of the Actuary in HHS, and the Congressional Budget Office. However, we note that if this assumption is rendered invalid by future Congressional action, the combination of positive and negative incentives in the HITECH Act are such that we believe adoption rates would differ from those estimated in this RIA.

There are many estimates of current EHR adoption and usage rates. There are at least two EHR functions—e-prescribing and billing—for which adoption and usage rates for both physicians and hospitals may exceed 50 percent. However, high estimates are misleading because they focus on particular elements, not on comprehensive systems that provide a full range of functions, similar in scope to those established in the companion interim final rule that adopts standards, implementation specifications, and certification criteria for the technical requirements and capabilities that EHR systems will need to meet in order to be certified. Based on several peer-reviewed studies, only a small proportion of physicians and hospitals have invested in EHR technology that encompasses such a broad range of functions. For example, a study entitled “Electronic Health Records in Ambulatory Care—A National Survey of Physicians” (Catherine DesRoches *et al.*, New England Journal of Medicine, July 3, 2008), found that in 2007 only “four percent of physicians reported having an extensive, fully functional electronic-records system, and 13 percent reported having a basic system.” (Additional results from the same survey can be found at the Department’s Health IT Adoption Initiative Web site at <http://healthit.hhs.gov/portal/server.pt?open=512&mode=2&cached=true&objID=1152>) Another study entitled “Use of Electronic Health Records in U.S. Hospitals” (Ashish Jha *et al.*, New England Journal of Medicine, April 16, 2009) found that in 2007 “only 1.5 percent of U.S. hospitals have a comprehensive electronic-records system * * * and an additional 7.6 percent have a basic system.” Computerized order entry for drugs was fully implemented in only 17 percent of hospitals.

Most physicians and hospitals have not yet invested in the hardware, software, testing and training to

implement EHRs for a number of reasons—lack of standards, lack of interoperability, limited physician acceptance, fear of maintenance costs, and lack of capital. Perhaps most importantly, adoption of EHR technology necessitates major changes in business processes and practices throughout a provider’s office or facility. Business process reengineering on such a scale is not undertaken lightly. However, the availability of the HITECH Act incentives, grants for technical support, more consistent use of standards and specified certification criteria, and other factors addressed in this RIA are sure to increase the adoption of EHR technology very substantially over the next 10 years—perhaps approaching complete adoption for physicians, hospitals, and many other types of providers.

Section II. of this proposed rule describes the categories of EPs, eligible hospitals, and CAHs under Medicare and Medicaid, and outlines the eligibility criteria, so those details are not repeated here.

Overall, we expect spending under the EHR incentive program for transfer payments to Medicare and Medicaid providers to be between \$14 and \$27 billion over 10 years (these estimates include net payment adjustments for providers who do not achieve meaningful use in 2015 and beyond in the amount of –\$2.3 billion to –\$5.1 billion). We have also estimated “per entity” costs for EPs and eligible hospitals, which aggregate to total spending. We estimate also that adopting entities will achieve dollar savings at least equal to their total costs, and that there will be additional benefits to society whose magnitude is uncertain, but will certainly be many billions of dollars over time.

While implementation costs will be significant for each participating entity, we anticipate that the short-term costs to demonstrate meaningful use of certified EHR technology will be outweighed by the long-term benefits, including practice efficiencies and improvements in medical outcomes. Although both cost and benefit estimates are highly uncertain, we have prepared a RIA that to the best of our ability presents the costs and benefits of the proposed rulemaking.

B. Regulatory Flexibility Analysis

The Regulatory Flexibility Act (RFA) requires agencies to prepare an Initial Regulatory Flexibility Analysis to describe and analyze the impact of 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 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 healthcare EPs, eligible hospitals, and CAHs are either non-profit 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 welcome comments on the analysis.

We believe that the adoption of EHRs will have an impact on virtually every EP and eligible hospital, as well as CAHs and some physicians and hospitals affiliated with MA plans. 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 will be subject to significant Medicare payment reductions after the fifth year. The anticipation of these Medicare payment adjustments will also motivate EPs, eligible hospitals, and CAHs to adopt and meaningfully use certified EHR technology.

For some EPs and eligible hospitals, the EHR technology that they have in place before the HITECH requirements, will be able to 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 will also require an upgrade to meet the HITECH certification requirements.

We believe that most EPs using EHR systems will require significant changes to achieve certification and/or the EPs will have to make process changes to achieve meaningful use. Further, given what we know about the current low levels of EHR adoption, we believe that the majority of EPs will need to purchase certified EHR technology and implement this new technology and have their staff trained 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. Additionally EPs and eligible hospitals will have to demonstrate meaningful use of their certified EHR technology as defined in the preamble. Since the definition for stage 1 meaningful use has not yet been finalized and may be altered due to public comment, it is difficult to determine how hard it will be for providers to achieve meaningful use.

1. Number of Small Entities

In total, we estimate that there are approximately 624,000 healthcare organizations (EPs or eligible hospitals) 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, eligible non-physicians (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 a certified EHR and \$10,000 annually for ongoing maintenance, while we estimate the hospitals will spend approximately \$5 million to purchase a certified EHR and \$1 million annually for ongoing maintenance. See the Assumptions section (section V.G.3 of this proposed rule) for details on our estimates for the number of entities that are eligible for the incentive, within each eligibility type category (EPs and eligible hospitals).

2. Alternatives Considered

This proposed rule implements new provisions of the Act for providing incentives for EPs, eligible hospitals, and CAHs that adopt and meaningfully use certified EHR technology. HHS has no discretion to change the incentive payments or payment reductions specified in the statute for providers that adopt or fail to adopt EHR and achieve meaningful use of EHR technology. The only substantial alternatives within the discretion of the Department revolve around how best to meet the requirements of the HITECH Act regarding requirements for

meaningful use for FY 2011 and beyond. Requirements that are too stringent could have the adverse effect of preventing many EPs, eligible hospitals, and CAHs from achieving meaningful use and thus preventing them from receiving an incentive payment. Our meaningful EHR use requirements for 2011 are designed to encourage more widespread adoption of certified EHR technology and allow more EPs, eligible hospitals, and CAHs to qualify for incentives while they are also adjusting their practice patterns and training staff to operate the EHR technology in preparation for more stringent meaningful use requirements over time. We recognize that there may be incremental costs that result from requiring additional functionality over the base level defined in the ARRA. For example, ARRA does not require certified EHRs to include functionalities associated with administrative simplification, but we have proposed them in this rule. We have not been able to find research that allows us to quantify these incremental costs and request comments on possible estimates or further sources of information that will help us develop estimates.

We note that with regard to reporting of quality measures for purposes of demonstrating meaningful use, we considered requiring EPs, eligible hospitals, and CAHs to report quality measures electronically in the initial year of the program; however, ultimately we determined that many providers would not be able to comply with a requirement to report all quality measures at the beginning of the program. The alternative approach, consistent with the requirements of this proposed rule, is to require reporting of quality measures in phases. In 2011, there will be a requirement to report quality measures through attestation with a numerator and denominator. Electronic quality measure reporting will begin in CY 2012. Additional quality measure reporting will be added in later years.

Under Medicaid, we considered numerous alternatives regarding how to demonstrate eligibility for the incentive payments as well as adoption and meaningful use of the certified EHR technology. These alternatives, including the period for demonstrating adequate patient volume, and the requirements and methods for demonstrating meaningful use are discussed in section II.D. of this proposed rule.

3. 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. (The statute provides for hardship exemption in such cases.) Accordingly, we believe that the object of the RFA to minimize burden on small entities are met by this rule as proposed. 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.

C. 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 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. This proposed rule would affect the operations of a substantial number of small rural hospitals because they are required to adopt certified EHR technology by 2015, or face adjusted payments. As stated above, 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.

D. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates would require spending in any 1 year \$100 million in 1995 dollars, updated annually for inflation. In 2009, that threshold is approximately \$130 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. 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 cost, 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 after FY 2015 are effectively mandates. We note that we have no discretion as to 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 \$130 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. We welcome comments on any aspects of this proposed rule that mandate costs that could be reduced or ameliorated.

E. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. 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 to administer the program. As previously stated, we believe that those administrative costs are minimal. We note that this proposed rule does add a new business requirement for States, because of the systems that will need to be

implemented to track and report on provider attestations, applications, and payments. States will also expend funds on the systems that must be built to conduct the tracking and reporting activities. However, the Federal share of the 90 percent match will protect the States from burdensome financial outlays.

F. Anticipated Effects

The objective of the remainder of this RIA is to summarize the costs and benefits of the HITECH incentive program for the Medicare FFS, Medicaid, and Medicare Advantage (MA) programs. We also provide assumptions and a narrative addressing the potential costs to the industry for implementation of this technology.

G. HITECH Impact Analysis

1. Need for Regulation

This proposed rule would implement the provisions of the American Recovery and Reinvestment Act of 2009 (ARRA) (Pub. L. 111–5) that provide incentive payments to eligible professionals (EPs) and eligible hospitals participating in Medicare and Medicaid programs that adopt and meaningfully use certified electronic health record (EHR) technology. The proposed rule would specify the—initial criteria an EP and eligible hospital must meet in order to qualify for the incentive payment; calculation of the incentive payment amounts; payment adjustments under Medicare for covered professional services and inpatient hospital services provided by EPs and eligible hospitals failing to meaningfully use certified EHR technology; and other program participation requirements.

2. Alternatives Considered

As previously discussed in the alternatives section of the regulatory flexibility analysis, HHS has no discretion to change the incentive payments or payment reductions specified in the statute for providers that adopt or fail to adopt EHR and achieve meaningful use of EHR technology. However, the Department has discretion around how best to meet the HITECH Act requirements for meaningful use for FY 2011 and beyond.

We recognize that there may be additional costs that result from various discretionary policy choices such as requiring additional functionality over the base level defined in the ARRA. For example, ARRA does not require certified EHRs to include functionalities associated with administrative simplification, but we have proposed them in this rule. While ARRA also

requires that certified EHRs have the capability to support CPOE, we have used our discretion in developing the “CPOE use” measure discussed in section III.

We have not been able to find research that allows us to quantify these incremental costs and request comments on possible estimates or further sources of information that will help us develop estimates (please refer to the analysis below as well as to the rightmost column in Table 33). In addition, we welcome information on benefits of specific provisions of this rule so that we can conduct, for the final rule, a more robust assessment of alternatives comparing incremental costs and benefits of each requirement.

3. 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 and 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 who are unable to demonstrate meaningful use starting in 2015; (2) the criteria for the demonstration of meaningful use of certified EHR technology have not been finalized and will change over time; (3) HHS has not yet defined certified EHR technology; (4) 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; and (5) the ultimate impact of certified EHR technology on expenditures for medical treatments (for example, reducing errors, expedited treatment) cannot be known with certainty at this time. The net costs and savings shown for this program represent a range of possible scenarios, and actual impacts could differ. We welcome public input on all aspects of the costs and benefits of this proposed rule.

As written in the preamble, this proposed rule describes the incentive payments for EPs, eligible hospitals, and CAHs for adopting and demonstrating meaningful use of certified EHR technology. This impact analysis addresses the costs and benefits to the Medicare and Medicaid programs, as

well as general implementation costs for eligible hospitals and EPs.

Detailed information about the incentive program, the specific payment amounts and how those payments will be paid, is provided in section II. of this proposed rule. Based on input from a number of internal and external sources, including the Government Accountability Office (GAO) and CBO, we calculated the numbers of EPs and eligible hospitals under Medicare, Medicaid, and MA and used them throughout the analysis.

- About 553,200 original Medicare FFS EPs in 2011 (some of which will also be Medicaid EPs).

- About 27 percent of the total EPs are hospital-based Medicare EPs, and are not eligible for the program. This leaves approximately 404,400 nonhospital-based Medicare EPs in 2011.

- Twenty percent of the nonhospital-based Medicare EPs (approximately 80,900 Medicare EPs in 2011) are also eligible for Medicaid (meet the 30 percent Medicaid patient volume criteria) but can only be paid under one program. Any EP in this situation will choose to receive the Medicaid incentive payment, because it is larger.

- About 38,200 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.

- 5,011 eligible hospitals, comprised of the following:

- ++ 3,620 acute care hospitals.
- ++ 1,302 CAHs (Medicare only).
- ++ 78 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.

- Payments can begin as early as FY 2011.

4. Industry Costs and Adoption Rates

To estimate the impact on healthcare providers we used information from four studies cited previously. Based on these studies, we estimate for EPs, 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. Though reports vary widely, we anticipate that the

average would be \$5 million for installation. We estimate \$1 million for maintenance, upgrades, and training each year. Though we cite these existing studies, we realize that these estimates vary widely, in part, because different providers have adopted different types of EHRs, each with their own set of functionalities. 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 types of EHRs used in these studies and the functionalities they contained. For that reason, we welcome industry input on the costs of implementing and maintaining certified EHR technology. We would be particularly interested in estimates of what a "qualified EHR" as defined in ARRA would cost (that is, an EHR with the capability to collect and store patient demographic data and support CPOE, clinical decision support, and registry functions) for both EPs and hospitals. To the extent that there may be additional costs that result from various discretionary policy choices in this rulemaking, such as requiring additional functionality over the base level defined in the ARRA, we would be interested to know what those incremental additional costs may be.

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. We welcome comments on our estimates, including costs estimates and adoption rate estimates.

For an eligible Medicaid EP, the first year incentive is based in part on the adoption, implementation, and upgrade costs. Previously, we noted that section 1903(t)(4)(C) of the Act gives the Secretary the authority to determine average allowable costs for certified EHR technology. The Secretary is to study average costs associated with the purchase, initial implementation, and upgrade of certified EHR technology, including support services and initial training.

Sections 1903(t)(1)(A) and 1903(t)(4) of the Act specify that EPs may not receive incentive payments in excess of

85 percent of the net average allowable costs of certified EHR technology, with such net average allowable costs capped at \$25,000 in the first year (for the purchase, implementation or upgrade of certified EHR technology) and \$10,000 in each of the subsequent years.

a. Costs of EHR Adoption for EPs

Previously, we described four studies used to estimate costs of implementation including the purchase and installation of hardware and software, training, as well as productivity losses associated with implementation and training. Each of these studies was conducted several years ago, and did not control for type of EHR, functionality, physician practice type or size. Furthermore, EHRs were not being built against any particular consensus standard, nor was the concept of "meaningful use" a factor. Thus, the cost of implementing and maintaining certified EHR technology which meets the requirements established in this regulation might exceed the estimates from these studies.

One average estimate of the cost per physician for implementation is around \$35,000. Therefore, in a practice with five physicians, the cost could be \$175,000. A similar study of community health centers estimated costs to average \$54,000 per physician FTE. In this study, the authors explained that implementation costs varied between entities for hardware, software, installation, and training. After implementation, there were ongoing operating costs estimated at \$21,000 per year for a practice of four physicians. The CBO 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. In the CBO study, operating costs added \$3,000 to \$9,000 per physician per year. Finally, a 2005 paper from AHRQ stated that the average purchase and implementation cost of an EHR could be \$32,606 per FTE physician. Maintenance costs were an additional \$1,500 per physician, per month, or \$18,000 per year. Smaller practices had the highest implementation costs per physician at \$37,204. Based on the studies cited, eligible providers will be eligible to receive the maximum incentive permitted under the statute, because the implementation and maintenance costs

we have estimated exceed the caps for net average allowable costs set in the statute.

In calculating the impact of the EHR incentive program for Medicaid EPs, we assumed that approximately 20 percent of the EPs eligible for the Medicare incentive payment program are also eligible for Medicaid EHR incentive payments (about 80,000 in 2011). Since the Medicaid incentive payments are higher than those for Medicare and EPs can only receive payments from one program, we assume the dually eligible EPs will receive their payments through the Medicaid program. Medicaid also offers incentive payments for pediatricians, dentists, certified nurse-midwives, nurse practitioners and certain physicians' assistants. While minimal, we have incorporated the sum of these groups in Table 51. We have estimated a range of Medicaid EPs that will be meaningful users each calendar year. The last line represents the range of predicted meaningful EHR users each calendar year. The Medicaid penetration rate for EPs is consistent with the analysis that was used for the Medicare EPs, but without the behavioral limitations imposed by the Medicare current statute SGR payment reductions. We assumed a modest behavioral response by Medicaid EPs to the Medicaid incentive payments resulting in an increase over baseline participation.

b. Costs of EHR Adoption for Eligible Hospitals

In 2006, the AHA conducted a survey to evaluate annual hospital costs: the range was enormous—ranging from \$30,500 to \$93.8 million, with a median amount of \$3.8 million. In another article from HealthDayNews, EHR system costs 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 AHA study, nearly 3,050 U.S. hospitals were surveyed about the use of EHR systems. Only 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. Almost eight percent of

hospitals had an EHR system that includes physician and nursing notes, but these systems did not have decision support. 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. Researchers found that 17 percent of the hospitals had the capacity for e-prescribing, a key feature in any modern day system. 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 is low, it is difficult to get a solid average estimate for implementation and maintenance costs that can be applied across the industry.

Although we have provided some estimates on implementation/upgrade costs in this analysis, 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, we invite public comment and additional information to assist in our analysis. We also note that there may be EPs that voluntarily choose not to participate in the program, and that those EPs may anticipate potential costs resulting from that decision. Therefore, we have set a placeholder in our accounting statement at this time and request public comment on industry costs on those that may or may not choose to implement the program that could inform our analysis for the final rule.

We did not include cost estimates on Federal hospitals in this analysis, since the Veterans Affairs hospitals have already implemented comprehensive electronic health record systems. There may be costs if those systems have to be significantly upgraded to meet the certification criteria, but no estimates were gathered for this analysis.

5. Medicare Incentive Program Costs

a. Medicare Eligible Professionals (EPs)

To determine the estimated costs of the Medicare incentives for EPs we first

needed to determine the EPs with Medicare claims. Then, we calculated that about 27 percent of those EPs are hospital-based based on the definition proposed in § 495.6, and therefore, do not qualify for incentive payments. They are subtracted from the total number of EPs who have claims with Medicare. These numbers were tabulated from Medicare claims data. We have also estimated that about 20 percent of EPs that are not hospital-based will qualify for Medicaid incentive payments and will choose that program because the payments are higher. Of the remaining EPs, we have 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, so we established high and low scenario to account for high and low rates of demonstration of meaningful use.

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 highly uncertain factor. Our Medicare EHR adoption assumptions for EPs are also affected by the current situation with Medicare physician fee schedule payment rates. As noted previously, under current law (that is, the SGR system formulas), physician payments will be reduced by at least 21 percent beginning in CY 2010. Such reductions would almost certainly 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 these very large payment reductions. Behavioral changes resulting from these scheduled payment reductions are not included in our estimate and likewise do not assume any additional behavioral changes from EHR incentive payments.

Accordingly, the estimated number of nonhospital based Medicare EPs who will demonstrate meaningful use of certified EHR technology over the period CYs 2011 through 2019 is as shown in Table 35.

TABLE 35—MEDICARE EPS DEMONSTRATING MEANINGFUL USE OF CERTIFIED EHR TECHNOLOGY, HIGH AND LOW SCENARIO

	Calendar year								
	2011	2012	2013	2014	2015	2016	2017	2018	2019
EPs who have claims with Medicare (thousands)	553.2	558.9	564.6	570.3	576.0	581.7	587.5	593.3	599.0
Non-Hospital Based EPs (thousands)	404.4	408.6	412.7	416.9	421.1	425.3	429.5	433.7	437.9
EPs that are both Medicare and Medicaid EPs (thousands)	80.9	81.7	82.5	83.4	84.2	85.1	85.9	86.7	87.6
Low Scenario:									
Percent of EPs who are Meaningful Users	10	13	15	18	21	24	28	32	36
Meaningful Users (thousands)	33.8	41.3	49.8	59.5	70.3	82.4	95.6	110.0	125.4
High Scenario:									
Percent of EPs who are Meaningful Users	36	40	44	49	53	58	62	66	70
Meaningful Users (thousands)	115.8	131.0	146.8	163.1	179.7	196.4	212.9	229.0	244.6

Under the HITECH Act, EPs can receive up to 5 years of Medicare incentive payments for the meaningful use of certified EHR technology. These payments are the lesser of 75 percent of the physician's allowed charges for the year or a specified maximum amount, which declines from a possible \$18,000 incentive payment for the first payment year to a \$2,000 incentive payment for the fifth payment year. EPs in HPSAs receive incentives that are 10 percent higher than the maximum amounts. Hospital-based EPs are not eligible for the Medicare EP incentive payments. EPs may choose to receive incentive payments from either Medicare or Medicaid, but not from both.

The standard full amount of Medicaid incentive payments that an EP could receive is larger than the standard full amount for the Medicare EP incentive payments: about \$65,000 versus \$44,000 for Medicare. Details about the Medicaid payments are described in the section V.G.3 of this proposed rule. Medicare incentive payments can first be paid to EPs in CY 2011; and 2012 is the last year that an EP can start to receive incentives and obtain the full 5 years of payments. EPs who first qualify in CY 2013 would be limited to an incentive of \$15,000 for the first year, and may be eligible to receive 4 years of incentive payments. EPs who first qualify in CY 2014 would be limited to an incentive of \$12,000 for the first year and may be eligible to receive 3 years of incentive payments. For the Medicare program, incentives are not

payable after CY 2016, and EPs who first demonstrate meaningful use in CY 2015 or later are not eligible for EHR incentive payments.

Medicare payment adjustments will apply in CY 2015 and later to EPs who cannot demonstrate meaningful use of certified EHR technology, regardless of whether they received an EHR incentive payment or not. Specifically, the Medicare Physician Fee Schedule payments for an EP who cannot demonstrate meaningful use of certified EHR technology would be reduced by 1 percentage point in CY 2015, two percentage points in CY 2016, and 3 percentage points in CY 2017, and between 3 and 5 percentage points in starting in CY 2018. The HITECH Act gives the Secretary the authority, beginning in CY 2018, to increase these reductions by 1 percentage point each year, but not more than 5 percentage points overall, if the Secretary finds the proportion of EPs who are meaningful EHR users is less than 75 percent.

Each year a transfer will be made between the general fund of the Treasury and the Part B account of the Supplemental Medical Insurance (SMI) trust fund to offset the incentives paid or payment adjustments made during the year. In this way, the Part B beneficiary premium will not be affected by the EP payment incentives.

We estimate that there are 12 MA plans that might be eligible to participate in the EHR incentive program. Those plans have about 28,000 EPs.

Our estimates of the incentive payment costs and payment adjustment savings 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 recent studies and discussions with subject matter experts. We project that a growing proportion of EPs will adopt certified EHR technology that meets the standards even in the absence of the legislated incentives. This number could be higher or lower depending on the final meaningful use definition adopted, physicians' access to capital and implementation expertise, the success of the other HITECH programs in reaching physicians, and other factors.

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). We took the estimated rate of

EHR adoption from the study with the most rigorous definition, assuming that meaningful use would be a standard at least as strict as that one (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). We then inflated that number (4 percent) to a 2011 baseline using the numbers of physicians reporting in that survey that they had EHR implementation

underway. We assumed that the same proportion of them would be implementing fully-functional EHRs as in the baseline (30 percent of those with basic systems.) We then trended this number forward using the trajectory mapped out by Ford *et al.* using the data from the period prior to FY 2004 since the slower rate of adoption during the FY 2005 through 2007 period was thought to be caused by policy uncertainty which this regulation should resolve.

However, actual adoption trends could be significantly different from these assumptions, given the elements of uncertainty we describe throughout this analysis.

The estimated net costs for the low scenario of the Medicare EP portion of the HITECH Act are shown in Table 36. This provision is estimated to decrease Part B expenditures by a net total of \$0.6 billion during FYs 2011 through 2019.

TABLE 36—ESTIMATED COSTS (+) AND SAVINGS (–) FOR MEDICARE EPs DEMONSTRATING MEANINGFUL USE OF CERTIFIED EHR TECHNOLOGY, LOW SCENARIO
[In billions]

Fiscal year	Incentive payments	Payment adjustment receipts	Benefit payments	Net total
2009
2010
2011	\$0.1	\$0.1
2012	0.9	0.9
2013	0.8	0.8
2014	0.7	0.7
2015	0.5	–\$0.4	0.1
2016	0.3	–0.6	–0.3
2017	0.1	–0.9	–0.8
2018	–1.0	–1.0
2019	–1.1	–1.1
Total, 2009–2014	2.4	2.4
Total, 2009–2019	3.2	–3.9	–0.6

The estimated net costs for the high scenario of the Medicare EP portion of

the HITECH Act are shown in Table 37. This provision is estimated to increase

Part B expenditures by a net total of \$5.4 billion during FYs 2011 through 2019.

TABLE 37—ESTIMATED COSTS (+) AND SAVINGS (–) FOR MEDICARE EPs DEMONSTRATING MEANINGFUL USE OF CERTIFIED EHR TECHNOLOGY, HIGH SCENARIO
[In billions]

Fiscal year	Incentive payments	Payment adjustment receipts	Benefit payments	Net total
2009
2010
2011	\$0.3	\$0.3
2012	2.2	2.2
2013	1.8	1.8
2014	1.5	1.5
2015	1.0	–\$0.2	0.8
2016	0.6	–0.3	0.2
2017	0.1	–0.5	–0.4
2018	–0.5	–0.5
2019	–0.5	–0.5
Total, 2009–2014	5.8	5.8
Total, 2009–2019	7.5	–2.1	5.4

b. Medicare Eligible Hospitals

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 assumption 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 \$9,000 to a high of \$10.4 million, with the median being \$3.6 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 2007 AHA annual 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 powerful 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 either neither CPOE or lab reporting. The CPOE for medication standard was chosen because expert input indicated that the CPOE standard in the proposed meaningful use definition will be the hardest one for hospitals to meet. Table 38 provides these proportions.

TABLE 38—HOSPITAL IT CAPABILITIES BY HOSPITAL SIZE

Hospital size	Levels of adoption							
	Any CPOE meds		Lab results		Neither		Total	
	Number of hospitals	Percentage	Number of hospitals	Percentage	Number of hospitals	Percentage	Number of hospitals	Percentage
CAHs	146	18	372	47	274	35	792	23
Small/Medium	683	30	1,268	55	359	16	2,310	67
Large (400+ beds)	169	49	162	47	17	5	348	10
Total	998	29	1802	52	650	19	3,450	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. We request public input on the costs of adoption and attaining the meaningful use standard and the determinants of those costs.

Under the HITECH Act, an eligible hospital can receive up to 4 years of Medicare incentive payments for the demonstration of meaningful use of certified EHR technology. These payments reflect the ratio of Medicare inpatient days to total inpatient days

and are adjusted by transition factors of 100, 75, 50, and 25 percent for the first through fourth implementation years respectively. Medicare incentive payments can first be paid to hospitals in FY 2011, and FY 2013 is the last year that a hospital can start to receive incentives and obtain the full 4-year transition rates. Eligible hospitals that first qualify in FY 2014 or FY 2015 will only receive the transition portions that apply to eligible hospitals who implement their EHR in FY 2013 (for example, 75 percent in FY 2014 and 50 percent in FY 2015). Eligible hospitals that first demonstrate meaningful use in FY 2016 or later are not eligible for incentive payments. Payment adjustments will be applied beginning in FY 2015 to eligible hospitals that

cannot demonstrate meaningful use of certified EHR technology. Special rules apply to CAHs.

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.

Again due to uncertainties, we are providing ranges for our estimates. Our high scenario estimated net costs for section 4102 of the HITECH Act are shown in Table 39: Estimated costs (+) and savings (–) for eligible hospitals adopting certified EHRs. This provision is estimated to increase Medicare hospital expenditures by a net total of \$11.2 billion during FYs 2011 through 2019.

TABLE 39—ESTIMATED COSTS (+) AND SAVINGS (–) FOR MEDICARE ELIGIBLE HOSPITALS DEMONSTRATING MEANINGFUL USE OF CERTIFIED EHR TECHNOLOGY, HIGH SCENARIO

[In billions]

Fiscal year	Incentive payments	Payment adjustment receipts	Benefit payments	Net total
2009
2010
2011	\$2.4	(1)	\$2.4
2012	2.7	(1)	2.7
2013	2.4	(1)	2.4
2014	2.3	(1)	2.3
2015	1.3	– \$0.1	(1)	1.2
2016	0.5	– 0.1	(1)	0.4
2017	(1)	(1)

TABLE 39—ESTIMATED COSTS (+) AND SAVINGS (–) FOR MEDICARE ELIGIBLE HOSPITALS DEMONSTRATING MEANINGFUL USE OF CERTIFIED EHR TECHNOLOGY, HIGH SCENARIO—Continued
[In billions]

Fiscal year	Incentive payments	Payment adjustment receipts	Benefit payments	Net total
2018	(¹)	(¹)
2019	(¹)	(¹)
Total, 2009–2014	9.8	–0.1	9.7
Total, 2009–2019	11.6	–\$0.2	–0.2	11.2

¹ Savings of less than \$50 million.

We are also providing the estimates for a low scenario in Table 40.

TABLE 40—ESTIMATED COSTS (+) AND SAVINGS (–) FOR MEDICARE ELIGIBLE HOSPITALS DEMONSTRATING MEANINGFUL USE OF CERTIFIED EHR TECHNOLOGY, LOW SCENARIO
[In billions]

Fiscal year	Incentive payments	Payment adjustment receipts	Benefit payments	Net total
2009
2010
2011	\$1.7	(¹)	\$1.7
2012	1.6	(¹)	1.6
2013	1.5	(¹)	1.5
2014	1.8	(¹)	1.8
2015	1.4	–\$0.4	(¹)	1.0
2016	0.6	–0.3	(¹)	0.3
2017	–0.3	(¹)	–0.3
2018	–0.2	(¹)	–0.2
2019	(¹)	(¹)
Total, 2009–2014	6.6	–\$0.1	6.5
Total, 2009–2019	8.6	–1.1	–0.2	7.4

¹ Savings of less than \$50 million.

Based on the comparison of Medicare incentive payments and implementation/operating costs for each eligible hospital (described above), we made the assumptions shown in Table 41, related to the prevalence of certified EHR technology for FY 2011 through

2018. 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 41 shows the high scenario estimates:

TABLE 41—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%
2011	0.8	0.5	0.3	0.2	0.1
2012	0.95	0.65	0.5	0.35	0.2
2013	1.0	0.8	0.7	0.6	0.4
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 50 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 2011. In FY 2012, 65 percent of those hospitals were assumed to have a certified EHR system. All such hospitals were assumed to have a certified EHR system in FY 2015 and thereafter.

High rates of EHR adoption are anticipated prior to FY 2015 due to the large payment adjustments that will be imposed on eligible hospitals that are unable to demonstrate meaningful use beginning in FY 2015. Specifically, the Medicare “market basket” payment

updates would be reduced (on a noncumulative basis) by one-fourth, one-half, and three-fourths for FYs 2015, 2016, and 2017 and later, respectively, for eligible hospitals that were not meaningful users of certified EHR technology. However, we heard 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, and so we provide a range which reflects what we believe are reasonably anticipated low to high rates of adoption.

Table 42 shows the low scenario estimates.

TABLE 42—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%
2011	0.6	0.35	0.2	0.2	0.05
2012	0.65	0.4	0.25	0.15	0.1
2013	0.75	0.55	0.4	0.25	0.15
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 42, 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 penalties. Nearly all eligible hospitals are projected to have implemented certified

EHR technology by FY 2019. Table 43 shows our high scenario estimated range of 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 43—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
2011	43.4	43.4
2012	58.5	58.5
2013	73.9	73.9
2014	84.8	84.8
2015	93.6	50.2
2016	97.3	35.1
2017	99.1
2018	100.0

For instance in FY 2012 under the high scenario, 58.5 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, 93.6 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 50.2 percent of all possible incentive payments actually paid in that year.

Table 44 shows the low scenario estimates.

TABLE 44—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
2011	30.5	30.5
2012	35.5	35.5
2013	46.2	46.2
2014	61.7	61.7
2015	77.8	47.3
2016	90.9	42.3
2017	94.5
2018	97.3

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 penalties 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 1,302 CAHs eligible to receive EHR incentives payments, and that will participate in the incentive program beginning in FY 2011. The statistics for their incentives are incorporated into the overall Medicare and Medicaid program costs.

6. Medicaid Incentive Program Costs

Under section 4201 of the HITECH Act, States can voluntarily participate in the Medicaid incentive payment program and we have based our Medicaid incentive program costs on all States participating. Eligible hospitals and EPs can also qualify for a Medicaid incentive payment for adopting, implementing, or upgrading and up to 5 years of incentive payments for demonstrating meaningful use certified EHR technology. Under Medicaid, EPs include physicians and pediatricians, dentists, certified nurse-midwives, nurse practitioners, and certain physician assistants. Initial incentive payments are available through 2016. The Medicaid hospital incentives are similar to those specified in section 4102 of the HITECH Act for Medicare, except that they are payable for up to 6 years based on the ratio of Medicaid inpatient days to total days, and are not phased down by the Medicare eligible hospital transition factors. Medicaid hospitals can begin incentive payments

through 2016. There are also additional hospitals, such as children's and cancer hospitals that are only eligible for Medicaid incentives.

EPs may qualify for Medicaid incentive payments if at least 30 percent of their patient volume is from Medicaid. (Separate rules apply for pediatricians.) As mentioned above, the Medicaid maximum incentive payments are larger than the corresponding Medicare payments. Various maximums are specified for eligible hospital and EP incentive payments. There are no Medicaid penalties for nonadoption of EHR systems or for failing to demonstrate meaningful use. 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 45 shows our high estimates for the net Medicaid costs for eligible hospitals and EP.

TABLE 45—ESTIMATED FEDERAL COSTS (+) AND SAVINGS (–) UNDER MEDICAID, HIGH SCENARIO
[In \$billions]

Fiscal year	Incentive payments		Benefit payments	Net total
	Hospitals	Eligible professionals		
2009
2010
2011	1.1	1.2	(¹)	2.3
2012	1.2	0.9	(¹)	2.1
2013	0.7	0.9	(¹)	1.6
2014	0.4	0.9	(¹)	1.3
2015	0.3	0.9	(¹)	1.2
2016	0.2	1.0	(¹)	1.2
2017	0.1	0.4	(¹)	0.5
2018	0.0	0.3	(¹)	0.3
2019	0.0	0.2	(¹)	0.2
Total, 2009–2014	3.4	3.8	0.0	7.2
Total, 2009–2019	4.1	6.6	–0.1	10.6

¹ Savings of less than \$50 million.

Table 46 shows the low estimates for Medicaid costs and savings.

TABLE 46—ESTIMATED FEDERAL COSTS (+) AND SAVINGS (–) UNDER MEDICAID, LOW SCENARIO
[In \$billions]

Fiscal year	Incentive payments		Benefit payments	Net total
	Hospitals	Eligible professionals		
2009
2010
2011	0.7	0.6	(¹)	1.3
2012	0.6	0.4	(¹)	1.0
2013	0.4	0.4	(¹)	0.9
2014	0.5	0.5	(¹)	1.0
2015	0.6	0.5	(¹)	1.1
2016	0.6	0.5	(¹)	1.1
2017	0.3	0.2	(¹)	0.5
2018	0.1	0.2	(¹)	0.2
2019	0.0	0.1	(¹)	0.1
Total, 2009–2014	2.3	1.9	0.0	4.2
Total, 2009–2019	3.8	3.5	–0.1	7.3

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 above, 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 that will be achieved. Therefore, as we estimated for the Medicare EPs, we are providing high and low scenario estimates for Medicaid EPs.

Our high scenario estimates are listed in the Table 47.

BILLING CODE 4120–01–P

TABLE 47: 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								
		2011	2012	2013	2014	2015	2016	2017	2018	2019
	EPs who have claims with Medicare	553.2	558.9	564.6	570.3	576.0	581.7	587.5	593.3	599.0
	Non Hospital –Based EPs (-27%)	404.4	408.6	412.7	416.9	421.1	425.3	429.5	433.7	437.9
A	EPs who meet the Medicaid patient volume threshold	80.9	81.7	82.5	83.4	84.2	85.1	85.9	86.7	87.6
B	Medicaid¹ only EPs	38.2	38.8	39.4	40.1	40.7	41.3	42.0	42.6	43.3
	Total Medicaid EPs (A + B)	119.1	120.5	122.0	123.4	124.9	126.4	127.9	129.3	130.8
	Percent of EPs receiving incentive payment during year	46.5%	61.6%	71.1%	76.8%	80.6%	84.3%	88.1%	91.9%	93.7%
	Number of EPs receiving incentive payment during year	55.4	74.2	86.7	94.8	100.7	106.6	112.7	118.9	122.6
	Percent of EPs who have ever received incentive payment	46.5%	61.6%	71.1%	76.8%	80.6%	84.3%	88.1%	91.9%	93.7%
	Number of EPs who have ever received incentive payment	55.4	74.2	86.7	94.8	100.7	106.6	112.7	118.9	122.6

¹ Includes non hospital-based eligible pediatricians, dentists, certified nurse-midwives, nurse practitioners and physicians assistants. This number is not based on the tabulated Medicare data. It was arrived at by computing a ratio of certified nurse-midwives to total nurse-midwives in the States of New York and New Jersey and then applying that ratio to the country to arrive at the total number of Medicaid certified nurse-midwives. This same logic was also used for nurse practitioners and physicians assistants. The number of pediatricians and dentists is based on Medicaid provider historical experience and available studies. It should also be noted that in computing the hospital-based percentages, the 27 percent used for physicians was not applied across all providers types since the information available indicated that individual hospital-based percentage for certified nurse-midwives is 26 percent, nurse practitioners is 28 percent, and physicians assistants is 48 percent. We chose New York and New Jersey because we were able to obtain data from those States. We welcome comments with additional data sources to further refine the estimates.

Under the high scenario, we assumed an increase over baseline participation of Medicaid EPs because of the incentive payments, with the proportion of EPs ever receiving incentive payments increasing from 46.5 percent in CY 2011 to 93.7 percent by CY 2019. About 55,000 EPs are projected to

qualify for incentive payments in CY 2011, resulting in a CY 2011 cost of about \$1.2 billion. 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 is a meaningful user or because he

or she is engaged in efforts to adopt, implement, or upgrade certified EHR technology, these participation rates include not only meaningful users but eligible providers implementing certified EHR technology as well. Table 48 shows our low scenario estimates.

TABLE 48: 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								
		2011	2012	2013	2014	2015	2016	2017	2018	2019
	EPs who have claims with Medicare	553.2	558.9	564.6	570.3	576.0	581.7	587.5	593.3	599.0
	Non Hospital – Based EPs (-27%)	404.4	408.6	412.7	416.9	421.1	425.3	429.5	433.7	437.9
A	EPs who meet the Medicaid patient volume threshold	80.9	81.7	82.5	83.4	84.2	85.1	85.9	86.7	87.6
B	Medicaid¹ only EPs	38.2	38.8	39.4	40.1	40.7	41.3	42.0	42.6	43.3
	Total Medicaid EPs (A + B)	119.1	120.5	122.0	123.4	124.9	126.4	127.9	129.3	130.8
	Percent of EPs receiving incentive payment during year	25.4%	30.8%	35.1%	38.6%	41.7%	45.1%	20.9%	15.3%	10.8%
	Number of EPs receiving incentive payment during year	30.2	37.1	42.9	47.6	52.1	57.0	26.7	19.8	14.1
	Percent of EPs who have ever received incentive payment	25.4%	30.8%	35.1%	38.6%	41.7%	45.1%	48.8%	52.8%	56.2%
	Number of EPs who have received ever incentive payment	30.2	37.1	42.9	47.6	52.1	57.0	62.4	68.3	73.5

¹Includes non hospital-based eligible pediatricians, dentists, certified nurse-midwives, nurse practitioners, and physicians assistants. This number is not based on the tabulated Medicare data. It was arrived at by computing a ratio of certified nurse-midwives to total nurse-midwives in the States of New York and New Jersey and then applying that ratio to the country to arrive at the total number of Medicaid certified nurse-midwives. This same logic was also used for nurse practitioners and physicians assistants. The number of pediatricians and dentists is based on Medicaid provider historical experience and available studies. It should also be noted that in computing the hospital-based percentages, the 27 percent used for physicians was not applied across all providers types since the information available indicated that individual hospital-based percentage for certified nurse-midwives is 26 percent, nurse practitioners is 28 percent, and physicians assistants is 48 percent. We chose New York and New Jersey because we were able to obtain data from those States. We welcome comments with additional data sources to further refine the estimates.

BILLING CODE 4120-01-C

b. Medicaid Hospitals

Medicaid incentive payments to most acute-care hospitals were estimated using the same adoption assumptions and methodology as described previously for Medicare eligible hospitals and shown in Table 49. 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 and children's hospitals can receive Medicaid incentive payments for no less than 3 years but no more than 6 years and 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.” 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 49—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
2011	60.7	60.7
2012	75.5	75.5
2013	86.0	86.0
2014	91.5	30.8
2015	96.3	20.8
2016	98.3	12.3
2017	99.5	6.8
2018	100.0	2.0
2019	100.0	0.0

Table 50 shows our low scenario estimates.

TABLE 50—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
2011	35.6	35.6
2012	40.6	40.6
2013	50.9	50.9
2014	66.8	31.2
2015	81.6	41.0
2016	92.6	41.7
2017	95.5	25.8
2018	97.4	11.0
2019	100.0	0.0

7. 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. We believe that the first 5 years of the incentive program will be dedicated to implementation activities, from installation of the technology to training to operational and behavioral changes. Information on the costs and benefits of adopting systems specifically meeting the requirements in this rule does not yet exist—and information on costs and benefits overall is limited (Goldzweig *et al.* 2009 “Costs and Benefits of Health Information Technology: New Trends from the Literature” *Health Affairs*.) We would welcome industry input on the impact of this proposed rule on adoption, the costs of adopting and meeting the meaningful use criteria, and on resulting benefits to providers.

Nonetheless, we believe there are benefits that can be obtained by eligible hospitals and EPs, including:

Reductions in medical recordkeeping costs, reductions in repeat tests, decreases in length of stay, and reduced errors. Furthermore, there is limited but growing evidence to support the cost saving benefits anticipated from wider adoption of EHRs. For example, at one hospital emergency room in Delaware, the ability to download and create a file with a patient’s medical history saved the ER \$545 per use, mostly on 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 Centers.) Some vendors have estimated that EHRs could result in cost savings of between \$100 and \$200 per patient per year. As 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.

Some vendors have estimated that EHRs could result in cost savings of between \$100 and \$200 per patient per year. As 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.

8. 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, they 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. Further, the report points out 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. 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. We would welcome additional data on the costs and benefits of specific provisions of this rule and the incentive program as a whole so that we can conduct, for the final rule, a more robust assessment of societal benefits to determine whether the benefits of the regulation justify its costs (as directed by Executive Order 12866).

9. General Considerations

The estimates for the HITECH Act provisions were based on the economic assumptions underlying the President's 2010 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 and EPs will adopt EHRs and other HIT. Nonetheless, we believe that the Medicare incentive payments and the prospect of significant payment penalties for nonparticipation 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 will administer the requirements in such a way as to encourage adoption of certified EHR technology and facilitate qualification for incentive payments, and will adopt progressively demanding standards each 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.

The CBO has estimated a modest level of such savings attributable to EHRs, with much of the amount associated with reductions in adverse drug-to-drug interactions. We believe that most of such savings will result from the existing statutory requirements for e-prescribing and that the acceleration of other efficiency savings will be relatively modest in comparison to the incentive and payment adjustments. 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.
- 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" (Giroso, 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, 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 at this time. 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. We invite comments on all of our assumptions.

All financial analysis is calculated over a 10-year planning horizon, because though the incentive payments for Medicare EPs, CAHs and eligible hospitals will only be paid for 5 years, the Medicaid incentives will cease in CY 2021. Starting in CY 2015, payment adjustments will be made to the Medicare physician fee schedule.

10. Summary

The total cost to the Medicare and Medicaid programs is estimated to be range from \$14.1 (low scenario) to 27.3 (high scenario) billion over a 10-year timeframe. 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 operations.

TABLE 51: Estimated EHR Incentive Payments and Benefits Impacts on the Medicare and Medicaid Programs of the HITECH EHR Incentive Program. (Fiscal Year) – (in billions) Low Scenario

Fiscal Year	Medicare Eligible		Medicaid Eligible		Total
	Hospitals	Professionals	Hospitals	Professionals	
2011	\$1.7	\$0.1	\$0.7	\$0.6	\$3.1
2012	\$1.6	\$0.9	\$0.6	\$0.4	\$3.5
2013	\$1.5	\$0.8	\$0.4	\$0.4	\$3.1
2014	\$1.8	\$0.7	\$0.5	\$0.5	\$3.5
2015	\$1.0	\$0.1	\$0.6	\$0.5	\$2.2
2016	\$0.3	-\$0.3	\$0.6	\$0.5	\$1.1
2017	-\$0.3	-\$0.8	\$0.3	\$0.2	-\$0.6
2018	-\$0.2	-\$1.0	\$0.1	\$0.2	-\$0.9
2019	—	-\$1.1	—	\$0.1	-\$1.0
TOTAL	\$7.4	-\$0.6	\$3.8	\$3.5	\$14.1

Table 53 shows the total costs from 2009 through 2019 for the high scenario after which the payment adjustments will be invoked.

Table 52: Estimated EHR Incentive Payments and Benefits Impacts on the Medicare and Medicaid Programs of the HITECH EHR Incentive Program. (Fiscal Year) – (in billions) High Scenario

Fiscal Year	Medicare Eligible		Medicaid Eligible		Total
	Hospitals	Professionals	Hospitals	Professionals	
2011	\$2.4	\$0.3	\$1.1	\$1.2	\$5.0
2012	\$2.7	\$2.2	\$1.2	\$0.9	\$7.0
2013	\$2.4	\$1.8	\$0.7	\$0.9	\$5.8
2014	\$2.3	\$1.5	\$0.4	\$0.9	\$5.1
2015	\$1.2	\$0.8	\$0.3	\$0.9	\$3.2
2016	\$0.4	\$0.2	\$0.2	\$1.0	\$1.8
2017	—	-\$0.4	\$0.1	\$0.4	\$0.1
2018	—	-\$0.5	—	\$0.3	-\$0.2
2019	—	-\$0.5	—	\$0.2	-\$0.3
TOTAL	\$11.2	\$5.4	\$4.1	\$6.6	\$27.3

11. 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, reduced errors and the like, unable to be quantified at this time. We invite public comment on the subject of

benefits to the Medicare and Medicaid programs.

H. 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 non-budgetary 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. We invite public comments that may inform additional analysis on the subject of industry costs

to implement EHR technology at the final rule stage.

**TABLE 53: Accounting Statement: Classification of Estimated Expenditures
CYs 2010 through 2019**

	Category: Transfers	
Annualized Monetized	Low Estimate	High Estimate
	7% 1,710.7 million	3,228.5 million
	3% 1,536.9 million	2,960.4 million
From Whom to Whom	Federal government to eligible professionals and hospitals.	
	Category: Industry Costs Associated with Reporting Requirements	
	Low Estimate	High Estimate
	626.62 million	652.35 million
From Whom to Whom	Private industry.	
	Category: Other Industry Costs	
Annualized Monetized	Low Estimate	High Estimate
	7% TBD	TBD
	3% TBD	TBD
From Whom to Whom	Private industry.	

In accordance with the provisions of Executive Order 12866, this proposed rule 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 422

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, 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 & Medicare Services proposed to amend 42 CFR Chapter IV as follows:

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 Methodology for Determining Prospective Payment Federal Rates for Inpatient Operating Costs

2. Section 412.64 is amended by—
A. Revising paragraph (d)(2)(i)(B).
B. Adding a new paragraph (d)(2)(i)(C) and (d)(3).

The revision and additions read as follows:

§ 412.64 Federal rates for inpatient operating costs for Federal fiscal year 2005 and subsequent fiscal years.

* * * * *

(d) * * *
(2) * * *
(i) * * *

(B) For fiscal year 2007 through 2014, by 2 percentage points.

(C) For fiscal year 2015 and subsequent fiscal years, by one-fourth.

* * * * *

(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, three-fourth of the applicable percentage change specified in paragraph (d)(1) of this section is reduced—

(i) For fiscal year 2015, by 33½ percent;

(ii) For fiscal year 2016, by 66⅔ percent; and

(iii) For fiscal year 2017 and subsequent fiscal years, by 100 percent.

* * * * *

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).

Subpart E—Payments to Providers

4. Section 413.70 is amended by—
A. Revising paragraph (a)(1).

B. Adding new paragraphs (a)(5) and (a)(6).

The revision and additions read as follows:

§ 413.70 Payment for services of a CAH.

(a) *Payment for inpatient services furnished by a CAH (other than services of distinct part units).* (1) Effective for cost reporting periods beginning on or after January 1, 2004, payment for inpatient services of a CAH, other than services of a distinct part unit of the CAH and other than the items included in the incentive payment described in paragraph (a)(5) of this section and subject to the adjustments described in paragraph (a)(6) of this section, is 101 percent of the reasonable costs of the CAH in providing CAH services to its inpatients, as determined in accordance with section 1861(v)(1)(A) of the Act and the applicable principles of cost reimbursement in this part and in Part 415 of this chapter, except that the following payment principles are excluded when determining payment for CAH inpatient services:

- (i) Lesser of cost or charges;
- (ii) Ceilings on hospital operating costs;
- (iii) Reasonable compensation equivalent (RCE) limits for physician services to providers; and
- (iv) The payment window provisions for preadmission services, specified in § 412.2(c)(5) of this subchapter and § 413.40(c)(2) of this part.

* * * * *

(5) A qualifying CAH receives an incentive payment for the reasonable costs of purchasing certified EHR technology in a cost reporting period during a payment year as determined under § 495.106 of this chapter in lieu of payment for such reasonable costs under paragraph (a)(1) of this section.

(6)(i) For cost reporting periods beginning in or after FY 2015, if a CAH is not a qualifying CAH, as defined in § 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:

(A) For cost reporting periods beginning in FY 2015, 100.66 percent;

(B) For cost reporting periods beginning in FY 2016, 100.33 percent; and

(C) For cost reporting periods beginning in FY 2017 and each subsequent fiscal year, 100 percent.

(ii) A CAH may, on a case-by-case basis, be exempt from the application of the adjustments made under this paragraph, if CMS or its Medicare

contractors determine, on an annual basis, that requiring the CAH to become a qualifying CAH under § 495.106 of this chapter would result in a significant hardship, such as in the case of a CAH in a rural area without sufficient Internet access.

(iii) In no case may a CAH be granted an exemption under this paragraph (a)(6) for more than 5 years.

(iv) There is no administrative or judicial review under section 1869 of the Act, section 1878 of the Act, or otherwise of the following:

(A) The methodology and standards for determining the amount of payment under paragraph (a)(5) of this section.

(B) The methodology and standards for determining the amount of payment adjustments made under this paragraph (a)(6).

(C) The methodology and standards for determining a CAH to be a qualifying CAH under § 495.106 of this chapter.

(D) The methodology and standards for determining if the hardship exemption applies to a CAH under paragraph (a)(6)(ii) of this section.

(E) The specification of the cost reporting periods, payment years, or fiscal years as applied under this paragraph.

(F) The calculation of reasonable costs under § 495.106(c) of this chapter.

* * * * *

PART 422—MEDICARE ADVANTAGE PROGRAM

5. The authority citation for part 422 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart G—Payments to Medicare Advantage Organizations

6. Section 422.304 is amended by adding a new paragraph (f) to read as follows:

§ 422.304 Monthly payments.

* * * * *

(f) *Separate payment for meaningful use of certified EHRs.* In the case of qualifying MA organizations, as defined in § 495.200 of this chapter, entitled to MA EHR incentive payments per § 495.220 of this chapter, such payments are made in accordance with sections 1853(l) and (m) of the Act and subpart C of Part 495 of this chapter.

7. Section 422.306 is amended by:

A. Removing “and” from the end of paragraph (b)(2)(ii);

B. Removing the period at the end of paragraph (b)(2)(iii) and adding “; and” in its place; and

C. Adding a new paragraph (b)(2)(iv) to read as follows:

§ 422.306 Annual MA capitation rates.

* * * * *

(b) * * *

(2) * * *

(iv) Adjusted to exclude costs attributable to payments under sections 1848(o) and 1886(n) of the Act of Medicare FFS incentive payments for meaningful use of electronic health records.

* * * * *

8. Section 422.308 is amended by—

A. Redesignating paragraph (a) as paragraph (a)(1).

B. Adding a new paragraph (a)(2). The addition reads as follows:

§ 422.308 Adjustments to capitation rates, benchmarks, bids, and payments.

* * * * *

(a) * * *

(2) The amount calculated in paragraph (a)(1) of this section must exclude expenditures attributable to sections 1848(a)(7) and (o) and sections 1886(b)(3)(B)(ix) and (n) of the Act.

* * * * *

9. Section 422.322 is amended by—

A. Adding paragraph (a)(3).

B. Revising paragraph (b).

§ 422.322 Source of payment and effect of MA plan election on payment.

(a) * * *

(3) Payments under subpart C of part 495 of this chapter for meaningful use of certified EHR technology are made from the Federal Hospital Insurance Trust Fund or the Supplementary Medical Insurance Trust Fund. In applying section 1848(o) of the Act under sections 1853(l) and 1886(n)(2) of the Act under section 1853(m) of the Act, CMS determines the amount to the extent feasible and practical to be similar to the estimated amount in the aggregate that would be payable for services furnished by professionals and hospitals under Parts B and A, respectively, under title XVIII of the Act.

(b) *Payments to the MA organization.* Subject to § 412.105(g), § 413.86(d), and § 495.204 of this chapter and §§ 422.109, 422.316, and 422.320, CMS' payments under a contract with an MA organization (described in § 422.304) with respect to an individual electing an MA plan offered by the organization are instead of the amounts which (in the absence of the contract) would otherwise be payable under original Medicare for items and services furnished to the individual.

* * * * *

SUBCHAPTER G—STANDARDS AND CERTIFICATIONS

10. A new part 495 is added to read as follows:

PART 495—STANDARDS FOR THE ELECTRONIC HEALTH RECORD TECHNOLOGY INCENTIVE PROGRAM

Subpart A—General Provisions

Sec.

- 495.2 Basis and purpose.
- 495.4 Definitions.
- 495.6 Meaningful use objectives measures for EPs, eligible hospitals, and CAHs.
- 495.8 Demonstration of meaningful use criteria
- 495.10 Participation requirements for EPs and eligible hospitals, and qualifying CAHs.

Subpart B—Requirements Specific to the Medicare Program

- 495.100 Definitions.
- 495.102 Incentive payments to EPs.
- 495.104 Incentive payments to eligible hospitals.
- 495.106 Incentive payments to CAHs.
- 495.108 Posting of required information.

Subpart C—Requirements Specific to Medicare Advantage (MA) Organizations

- 495.200 Definitions.
- 495.202 Identification of qualifying MA organizations, MA-EPs, and MA-affiliated eligible hospitals.
- 495.204 Incentive payments to qualifying MA organizations for MA-EPs and hospitals.
- 495.206 Timeframe for payment to qualifying MA organizations.
- 495.208 Avoiding duplicate payment.
- 495.210 Meaningful user attestation.
- 495.212 Limitation on review.

Subpart D—Requirements Specific to the Medicaid Program

- 495.300 Basis and purpose.
- 495.302 Definitions.
- 495.304 Medicaid provider scope and eligibility.
- 495.306 Establishing patient volume.
- 495.308 Net average allowable costs as the basis for determining the incentive payment.
- 495.310 Medicaid provider incentive payments.
- 495.312 Process for payments.
- 495.314 Activities required to receive an incentive payment.
- 495.316 State monitoring and reporting regarding activities required to receive an incentive payment.
- 495.318 State responsibilities for receiving FFP.
- 495.320 FFP for payments to Medicaid providers.
- 495.322 FFP for reasonable administrative expenses.
- 495.324 Prior approval conditions.
- 495.326 Disallowance of Federal financial participation (FFP).
- 495.328 Request for reconsideration of adverse determination.
- 495.330 Termination of Federal financial participation (FFP) for failure to provide access to information.
- 495.332 State Medicaid (HIT) plan requirements.
- 495.334 State self-assessment requirements.

- 495.336 Health information technology planning advance planning document requirements (HIT PAPD).
- 495.338 Health information technology implementation advance planning document requirements (HIT IAPD).
- 495.340 As-needed HIT PAPD update and as-needed HIT IAPD update requirements.
- 495.342 Annual HIT IAPD requirements.
- 495.344 Approval of the State Medicaid HIT plan, the HIT PAPD and update, the HIT IAPD and update, and the annual HIT IAPD.
- 495.346 Access to systems and records.
- 495.348 Procurement standards.
- 495.350 State Medicaid agency attestations.
- 495.352 Reporting requirements.
- 495.354 Rules for charging equipment.
- 495.356 Nondiscrimination requirements.
- 495.358 Cost allocation plans.
- 495.360 Software and ownership rights.
- 495.362 Retroactive approval of FFP with an effective date of February 18, 2009.
- 495.364 Review and assessment of administrative activities and expenses of Medicaid provider health information technology adoption and operation.
- 495.366 Financial oversight and monitoring of expenditures.
- 495.368 Combating fraud and abuse.
- 495.370 Appeals process for a Medicaid provider receiving electronic health record incentive payments.

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart A—General Provisions

§ 495.2 Basis and purpose.

This part implements the following:

(a) Section 1848(o) of the Act by establishing payment incentives under Medicare Part B for physicians and other professionals who adopt and meaningfully use certified electronic health record technology.

(b) Section 1853(1) of the Act to provide incentive payments to Medicare Advantage organizations for their affiliated professionals who meaningfully use certified EHR technology and meet certain other requirements.

(c) Section 1886(n) of the Act by establishing incentives payments for the meaningful use of certified EHR technology by subsection (d) hospitals, as defined under section 1886(d)(1)(B) of the Act, participating in Medicare FFS program.

(d) Section 1814(l) of the Act to provide an incentive payment to critical access hospitals who meaningfully use certified EHR technology based on the hospitals' reasonable costs.

(e) Section 1853(m) of the Act to provide incentive payments to MA organizations for certain affiliated hospitals that meaningfully use certified EHR technology.

(f) Sections 1903(a)(3)(F) and 1903(t) of the Act to provide 100 percent Federal financial participation (FFP) to States for incentive payments to certain eligible providers participating in the Medicaid program to purchase, implement, and operate (including support services and training for staff) certified EHR technology and 90 percent FFP for State administrative expenses related to such incentive payments.

(g) Sections 1848(a)(7), 1853(l)(4), 1886(b)(3)(ix)(1), and 1853(m)(4) of the Act, providing for payment reductions for inpatient services furnished on or after October 1, 2014 to Medicare beneficiaries by hospitals that are not meaningful users of certified electronic health record technology, and for covered professional services furnished on or after January 1, 2015 to Medicare beneficiaries by physicians and other professionals who are not meaningful users of certified electronic health record technology.

§ 495.4 Definitions.

In this part, unless otherwise indicated—

Certified electronic health record technology means a qualified EHR that meets the certification requirements specified in 45 CFR 170.102.

Critical access hospital (CAH) means a facility that has been certified as a critical access hospital under section 1820(e) of the Act and for which Medicare payment is made under section 1814(l) of the Act for inpatient services and under section 1834(g) of the Act for outpatient services.

EHR reporting period means either of the following:

(1) For an EP—

(i) For the first payment year, any continuous 90-day period within a calendar year;

(ii) For the second, third, fourth, fifth or sixth payment year, the calendar year.

(2) For an eligible hospital or a CAH—

(i) For the first payment year, any continuous 90-day period within a fiscal year; and

(ii) For the second, third, fourth, fifth or sixth payment year, the fiscal year.

Eligible hospital means an eligible hospital as defined under § 495.100 or Medicaid eligible hospital under subpart D of this part.

Eligible professional (EP) means an eligible professional as defined under § 495.100 or a Medicaid eligible professional under subpart D of this part.

Fifth payment year means the fifth payment year that the EP, eligible hospital or CAH receives an incentive payment under this part.

First payment year means the first payment year that the EP, eligible hospital or CAH receives an incentive payment under this part.

Fourth payment year means the fourth payment year that the EP, eligible hospital or CAH receives an incentive payment under this part.

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 the CY preceding the payment year in a hospital setting. A setting is considered a hospital setting if it is identified by the codes used in the HIPAA standard transactions that identifies the site of service as an inpatient hospital, outpatient hospital, or emergency room.

Meaningful EHR user means—

(1) An EP, eligible hospital or CAH that, for an EHR reporting period for a payment 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

(2) A Medicaid EP or Medicaid eligible hospital, that meets paragraph (1) of this definition and any additional criteria for meaningful use imposed by the State and approved by CMS under § 495.316 and § 495.332.

Payment year means—

(1) For an EP other than a Medicaid EP, a calendar year beginning with CY 2011; and

(2) For a CAH or an eligible hospital other than a Medicaid eligible hospital, a Federal fiscal year beginning with FY 2011.

(3) For a Medicaid EP,

(i) The timeframe specified in paragraph (1) of this definition; or

(ii) In accordance with subpart D of this part and with CMS approval, CY 2010.

(4) For a Medicaid eligible hospital,

(i) The timeframe specified in paragraph (2) of this definition; or

(ii) In accordance with subpart D of the part and with CMS approval, FY2010.

Qualified EHR means an electronic record of health related information on an individual that includes patient demographic and clinical health information, such as medical history and problem lists; and has the capacity to meet all of the following:

(1) Provide clinical decision support.
(2) Support physician order entry.
(3) Capture and query information relevant to health care quality.

(4) To exchange electronic health information with, and integrate such information from other sources.

Second payment year means the second payment year that the EP,

eligible hospital or CAH receives an incentive payment under this part.

Sixth payment year means the sixth payment year that the EP, eligible hospital or CAH receives an incentive payment under this part.

Third payment year means the third payment year that the EP, eligible hospital or CAH receives an incentive payment under this part.

§ 495.6 Meaningful use objectives and measures for EPs, eligible hospitals, and CAHs.

(a) *Stage 1 criteria for EPs*—(1) *General rule regarding Stage 1 criteria for meaningful use for EPs.* Except as specified in paragraph (a)(2) of this section, EPs must meet all objectives and associated measures of the Stage 1 criteria specified in paragraphs (c) and (d) of this section to receive an incentive payment.

(2) *Exceptions for Medicaid EPs*—(i) *Exception for Medicaid EPs receiving payment in CY 2010.* If CMS has approved a State's request to begin providing incentive payments to EPs in CY 2010 for adopting, implementing or upgrading certified EHR technology, the objectives and associated measures of the Stage 1 criteria specified in paragraphs (c) and (d) are applicable to an EP whose second payment year is CY 2011.

(ii) *Exception for Medicaid EPs who adopt, implement or upgrade in their first payment year.* For Medicaid EPs who adopt, implement, or upgrade certified EHR technology in their first payment year, the meaningful use objectives and associated measures of the Stage 1 criteria specified in paragraphs (c) and (d) apply beginning with the second payment year, and do not apply to the first payment year.

(b) *Stage 1 criteria for eligible hospitals and CAHs*—(1) *General rule regarding Stage 1 criteria for meaningful use for eligible hospitals or CAHs.* Except as specified in paragraph (b)(2) of this section, eligible hospitals and CAHs must meet all objectives and associated measures of the Stage 1 criteria specified in paragraphs (c) and (e) of this section to receive an incentive payment.

(2) *Exception for Medicaid eligible hospitals.* For Medicaid eligible hospitals who adopt, implement, or upgrade certified EHR technology in their first payment year, the meaningful use objectives and associated measures of the Stage 1 criteria specified in paragraphs (c) and (e) apply beginning with the second payment year.

(c) *Stage 1 criteria for EPs and eligible hospitals or CAHs.* An EP, eligible hospital or CAH must satisfy the

following objectives and associated measures:

(1)(i) *Objective.* Implement drug-drug, drug-allergy, drug-formulary checks.

(ii) *Measure.* The EP, eligible hospital or CAH has enabled this functionality.

(2)(i) *Objective.* Maintain an up-to-date problem list of current and active diagnoses based on ICD-9-CM or SNOMED CT ®.

(ii) *Measure.* At least 80 percent of all unique patients seen by the EP or admitted to an eligible hospital or CAH have at least one entry or an indication of none recorded as structured data.

(3)(i) *Objective.* Maintain active medication list.

(ii) *Measure.* At least 80 percent of all unique patients seen by the EP or admitted by the eligible hospital or CAH have at least one entry (or an indication of "none" if the patient is not currently prescribed any medication) recorded as structured data.

(4)(i) *Objective.* Maintain active medication allergy list.

(ii) *Measure.* At least 80 percent of all unique patients seen by the EP or admitted to the eligible hospital or CAH have at least one entry (or an indication of "none" if the patient has no medication allergies) recorded as structured data.

(5)(i) *Objective.* Record the following demographics:

(A) Preferred language.

(B) Insurance type.

(C) Gender.

(D) Race.

(E) Ethnicity.

(F) Date of birth.

(G) For eligible hospitals or CAHs, the date and cause of death in the event of mortality.

(ii) *Measure.* At least 80 percent of all unique patients seen by the EP or admitted to the eligible hospital or CAH have the demographics specified in paragraphs (c)(5)(i)(A) through (G) of this section recorded as structured data.

(6)(i) *Objective.* (A) Record and chart changes in the following vital signs:

(1) Height.

(2) Weight.

(3) Blood pressure.

(B) Calculate and display the body mass index (BMI) for patients 2 years and older.

(C) Plot and display growth charts for children 2 to 20 years including body mass index.

(ii) *Measure.* For at least 80 percent of all unique patients age 2 years or older seen by the EP or admitted to the eligible hospital, record blood pressure and BMI and plot the growth chart for children age 2 to 20 years old.

(7)(i) *Objective.* Record smoking status for patients 13 years old or older.

(ii) *Measure*. At least 80 percent of all unique patients 13 years old or older seen by the EP or admitted to the eligible hospital or CAH have "smoking status" recorded.

(8)(i) *Objective*. Incorporate clinical lab-test results into EHR as structured data.

(ii) *Measure*. At least 50 percent of all clinical lab tests results ordered by the EP or authorized provider of the hospital 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.

(9)(i) *Objective*. Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, research and outreach.

(ii) *Measure*. Generate at least one report listing patients of the EP, eligible hospital or CAH with a specific condition.

(10)(i) *Objective*. Implement five clinical decision support rules relevant to specialty or high clinical priority, including for diagnostic test ordering, along with the ability to track compliance with those rules.

(ii) *Measure*. Implement five clinical decision support rules relevant to the clinical quality metrics reported under this subpart.

(11)(i) *Objective*. Check insurance eligibility electronically from public and private payers.

(ii) *Measure*. Insurance eligibility is checked electronically for at least 80 percent of all unique patients seen by the EP or admitted to the eligible hospital or CAH.

(12)(i) *Objective*. Submit claims electronically to public and private payers.

(ii) *Measure*. At least 80 percent of all claims filed electronically by the EP or the eligible hospital or CAH.

(13)(i) *Objective*. Perform medication reconciliation at relevant encounters and each transition of care.

(ii) *Measure*. Perform medication reconciliation for at least 80 percent of relevant encounters and transitions of care.

(14)(i) *Objective*. Provide summary care record for each transition of care and referral.

(ii) *Measure*. Provide summary of care record for at least 80 percent of transitions of care and referrals.

(15)(i) *Objective*: Capability to submit electronic data to immunization registries and actual submission where required and accepted.

(ii) *Measure*: Performed at least one test of certified EHR technology's capability to submit electronic data to immunization registries.

(16)(i) *Objective*. Capability to provide electronic syndromic surveillance data to public health agencies and actual transmission according to applicable law and practice.

(ii) *Measure*. Performed at least one test of certified EHR technology's capacity to provide electronic syndromic surveillance data to public health agencies (unless none of the public health agencies to which the EP, eligible hospital or CAH submits such information have the capacity to receive the information electronically).

(17)(i) *Objective*. Protect electronic health information created or maintained by 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) and implement security updates as necessary.

(d) *Additional Stage 1 criteria for EPs*. An EP must meet the following objectives and associated measures:

(1)(i) *Objective*. Use computerized provider order entry (CPOE).

(ii) *Measure*. CPOE is used for at least 80 percent of all orders.

(2)(i) *Objective*. Generate and transmit permissible prescriptions electronically (eRx).

(ii) *Measure*. At least 75 percent of all permissible prescriptions written by the EP are transmitted electronically using certified EHR technology.

(3)(i) *Objective*. Report ambulatory quality measures to CMS or, in the case of Medicaid EPs, the States.

(ii) *Measure*. Successfully report to CMS (or, in the case of Medicaid EPs, the States) clinical quality measures in the form and manner specified by CMS.

(4)(i) *Objective*. Send reminders to patients per patient preference for preventive/follow-up care.

(ii) *Measure*. Reminder sent to at least 50 percent of all unique patients seen by the EP that are 50 years of age and over.

(5)(i) *Objective*. Provide patients with an electronic copy of their health information (including diagnostic test results, problem list, medication lists, and allergies) upon request.

(ii) *Measure*. At least 80 percent of all patient requests for an electronic copy of their health information are provided it within 48 hours.

(6)(i) *Objective*. Provide patients with timely electronic access to their health information (including diagnostic test results, problem list, medication lists, and allergies) within 96 hours of the information being available to the EP.

(ii) *Measure*. At least 10 percent of all unique patients seen by the EP are provided timely electronic access to their health information.

(7)(i) *Objective*. Provide clinical summaries to patients for each office visit.

(ii) *Measure*. Clinical summaries provided to patients for at least 80 percent of all office visits.

(8)(i) *Objective*. Capability to exchange key clinical information among providers of care and patient authorized entities electronically.

(ii) *Measure*. Perform at least one test of certified EHR technology's capacity to electronically exchange key clinical information.

(e) *Additional Stage 1 criteria for eligible hospitals or CAHs*. Eligible hospitals or CAHs must meet the following objectives and associated measures:

(1)(i) *Objective*. Use computerized provider order entry (CPOE) for orders (any type) directly entered by authorizing provider (for example, MD, DO, RN, PA, NP).

(ii) *Measure*. CPOE is used for at least 10 percent of all orders.

(2)(i) *Objective*. Report hospital quality measures to CMS or, in the case of Medicaid eligible hospitals, the States.

(ii) *Measure*. Successfully report to CMS (or, in the case of Medicaid eligible hospitals, the States) clinical quality measures in the form and manner specified by CMS.

(3)(i) *Objective*. Provide patients with an electronic copy of their health information (including diagnostic test results, problem list, medication lists, allergies, discharge summary, and procedures), upon request.

(ii) *Measure*. At least 80 percent of all patient requests for an electronic copy of their health information are provided it within 48 hours

(4)(i) *Objective*. Provide patients with an electronic copy of their discharge instructions and procedures at time of discharge, upon request.

(ii) *Measure*. At least 80 percent of all patients who are discharged from an eligible hospital or CAH and who request an electronic copy of their discharge instructions and procedures are provided it.

(5)(i) *Objective*. Capability to exchange key clinical information (for example, discharge summary, procedures, problem list, medication list, allergies, and diagnostic test results) among providers of care and patient-authorized entities electronically.

(ii) *Measure*. Performed at least one test of certified EHR technology's capacity to electronically exchange key clinical information.

(6)(i) *Objective*. Capability to provide electronic submission of reportable lab results (as required by State or local

law) to public health agencies and actual submission where it can be received.

(ii) *Measure*. Performed at least one test of certified EHR technology capacity to provide electronic submission of reportable lab results to public health agencies (unless none of the public health agencies to which the eligible hospital submits such information have the capacity to receive the information electronically).

§ 495.8 Demonstration of meaningful use criteria.

(a) *Demonstration by EPs*. An EP must demonstrate that he or she satisfies each of the applicable objectives and associated measures under § 495.6 of this subpart as follows:

(1) For CY 2011,

(i) Attest, through a secure mechanism, in a manner specified by CMS (or for a Medicaid EP, in a manner specified by the State), that during the EHR reporting period, the EP used certified EHR technology, and specify the technology used.

(ii) Attest, through a secure mechanism, in a manner specified by CMS (or for a Medicaid EP, in a manner specified by the State), that during the EHR reporting period, the EP satisfied each of the applicable objectives and associated measures under § 495.6 of this part. The EP must specify the EHR reporting period and provide the result of each applicable measure for all patients seen during the EHR reporting period for which a selected measure is applicable.

(iii) For Medicaid EPs, if, in accordance with § 495.316 and § 495.332, CMS has approved a State's additional criteria for meaningful use, demonstrate meeting such criteria using the method approved by CMS.

(iv) *Exception for Medicaid EPs*. If a Medicaid EP has adopted, implemented or upgraded certified EHR technology described in § 495.4 of this subpart, the provider must demonstrate meaningful use in the second payment year as described in § 495.6 and § 495.8 of this subpart.

(2) For CY 2012 and subsequent years—

(i) Attest, through a secure mechanism, in a manner specified by CMS (or for a Medicaid EP, in a manner specified by the State) that during the EHR reporting period, the EP used certified EHR technology and specify the technology used.

(ii) Attest, through a secure mechanism, in a manner specified by CMS (or for a Medicaid EP, in a manner specified by the State), that during the EHR reporting period, the EP satisfied

each of the applicable objectives and associated measures under § 495.6, except § 495.6(d)(3) "Report ambulatory quality measures to CMS or, in the case of Medicaid EPs, the States."

(iii) For § 495.6(d)(3), "Report ambulatory quality measures to CMS or, in the case of Medicaid EPs, the States", report electronically to CMS (or in the case of Medicaid EPs, the States) clinical quality information in the form and manner specified by CMS.

(iv) For Medicaid EPs, if, in accordance with § 495.316 and § 495.332, CMS has approved a State's additional criteria for meaningful use, demonstrate meeting such criteria using the method approved by CMS.

(b) *Demonstration by eligible hospitals and CAHs*. To successfully demonstrate meaningful use an eligible hospital or CAH must the following requirements:

(1) For FY 2011—

(i) Attest, through a secure mechanism, in a manner specified by CMS (or for a Medicaid eligible hospital, in a manner specified by the State), that during the EHR reporting period, the eligible hospital or CAH used certified EHR and specify the technology used.

(ii) Attest, through a secure mechanism, in a manner specified by CMS (or for a Medicaid eligible hospital, in a manner specified by the State), that during the EHR reporting period, the eligible hospital or CAH satisfied each of the applicable objectives and associated measures under § 495.6. The eligible hospital or CAH must specify the EHR reporting period and provide the result of each applicable measure for all patients admitted to the eligible hospital during the EHR reporting period for which a selected measure is applicable.

(iii) *Exception for Medicaid eligible hospitals*. If a Medicaid eligible hospital has adopted, implemented or upgraded certified EHR technology for the first payment year, the eligible hospital must demonstrate meaningful use in the second payment year, see § 495.6 and § 495.8.

(iv) For hospitals participating in the Medicaid EHR incentive program, if, in accordance with § 495.316 and § 495.332, CMS has approved a State's additional criteria for meaningful use, demonstrate meeting such criteria using the method approved by CMS.

(2) For FY 2012 and subsequent years must—

(i) Attest, through a secure mechanism, in a manner specified by CMS (or for a Medicaid eligible hospital, in a manner specified by the State), that during the EHR reporting period, the

eligible hospital or CAH used certified EHR and specify the technology used.

(ii) Attest, through a secure mechanism, in a manner specified by CMS (or for a Medicaid eligible hospital, in a manner specified by the State), that during the EHR reporting period, the eligible hospital or CAH satisfied each of the applicable objectives and associated measures under § 495.6 except § 495.6(e)(2). The eligible hospital or CAH must specify the EHR reporting period and provide the result of each applicable measure, except for § 495.6(e)(2) "Report hospital quality measures to CMS or, in the case of Medicaid eligible hospitals, the States:"

(iii) For § 495.6(e)(2) "Report hospital clinical quality measures to CMS or, in the case of Medicaid eligible hospitals, the States," report electronically to CMS (or in the case of Medicaid eligible hospitals, the States), clinical quality measures in the form and manner specified by CMS.

(iv) For Medicaid hospitals if, in accordance with § 495.316 and § 495.332, CMS has approved a State's additional criteria for meaningful use, demonstrate meeting such criteria using the method approved by CMS.

(c) *Review of meaningful use*. (1) CMS may review an EP, eligible hospital or CAH's demonstration of meaningful use.

(2) EPs, eligible hospitals, and CAHs must keep documentation supporting their demonstration of meaningful use for 10 years.

§ 495.10 Participation requirements for EPs, eligible hospitals, and CAHs.

(a) An eligible hospital, CAH or EP must submit in a manner specified by CMS the following information in the first payment year:

(1) Name of the EP, eligible hospital or CAH.

(2) National Provider Identifier (NPI).

(3) Business address and phone number.

(b) In addition to the information submitted under paragraph (a) of this section, an eligible hospital or CAH, must, in the first payment year, submit in a manner specified by CMS its CMS Certification Number (CCN) and its Taxpayer Identification Number (TIN).

(c) Subject to paragraph (f) of this section, in addition to the information submitted under paragraph (a) of this section, an EP must submit in a manner specified by CMS, the Taxpayer Identification Number (TIN) to which the EP's incentive payment should be made.

(d) In the event the information specified in paragraphs (a) through (c) of this section as previously submitted to CMS is no longer accurate, the EP or

eligible hospital must provide updated information to CMS or the State on a timely basis in the manner specified by CMS or the State.

(e) An EP that qualifies as both a Medicaid EP and Medicare EP—

(1) Must notify CMS in the manner specified by CMS as to whether he or she elects to participate in the Medicare or the Medicaid EHR incentive program.

(2) Is limited to switching between programs one time, and only for payment years 2014 and before;

(3) Must, for each payment year, meet all of the Medicare or Medicaid applicable requirements, including applicable patient volume requirements, for the program he or she chooses to participate in;

(4) Is limited to receiving, in total, the maximum payments the EP would receive under the Medicaid EHR program, as described in subpart D of this part;

(5) Is placed in the payment year the EP would have been in, had the EP not switched programs. For example, an EP that begins receiving Medicaid incentive payments in 2011, and then switches to the Medicare program for 2012, is in his or her second payment year in 2012.

(f) Limitations on incentive payment reassignments. Section 1842(b)(6)(A) of the Act allows for the reassignment of payments under Medicare to an employer or entity with which the EP has a contractual arrangement allowing the employer or entity to bill and receive payment for the EP's covered professional services.

(1) EPs are permitted to reassign their incentive payments to their employer or to an entity with which they have a contractual arrangement, consistent with all rules governing reassignments including part 424, subpart F of this chapter.

(2) Each EP may only reassign the entire amount of the incentive payment to one employer or entity.

Subpart B—Requirements Specific to the Medicare Program

§ 495.100 Definitions.

In this subpart unless otherwise indicated—

Covered professional services means services furnished by an eligible professional for which payment is made under, or is based on, the Medicare physician fee schedule as provided in section 1848(k)(3) of the Act.

Eligible hospital means a hospital subject to the prospective payment system specified in § 412.1(a)(1) of this chapter, excluding those hospitals specified in § 412.23 of this chapter.

Eligible professional (EP) means a physician as defined in section 1861(r)

of the Act, which includes all of the following types of professionals:

(1) A doctor of medicine or osteopathy.

(2) A doctor of dental surgery or medicine.

(3) A doctor of podiatric medicine.

(4) A doctor of optometry.

(5) A chiropractor.

Geographic health professional shortage area (HPSA) means an area that is designated by the Secretary under section 332(a)(1)(A) of the PHS Act as of December 31 of the year prior to the payment year as having a shortage of health professionals.

Qualifying CAH means a CAH that is a meaningful EHR user for the EHR reporting period for a cost reporting period beginning during a payment year.

Qualifying eligible professional (EP) means an EP who is a meaningful EHR user for the EHR reporting period for a payment year and who is not a hospital-based EP.

Qualifying hospital means an eligible hospital that is a meaningful EHR user for the EHR reporting period for a payment year.

§ 495.102 Incentive payments to EPs.

(a) *General rules.* (1) Subject to paragraph (b) of this section, in addition to the amount otherwise paid under section 1848 of the Act, there shall be paid to a qualifying eligible professional (or to an employer or entity in the cases described in section 1842(b)(6)(A) of the Act) for a payment year an amount equal 75 percent of the estimated allowed charges under the physician fee schedule (established under section 1848 of the Act) for the covered professional services furnished by the EP during the payment year.

(2) For purposes of this paragraph (a), the estimated allowed charges for the qualifying EP's covered professional services during the payment year are determined based on claims submitted no later than 2 months after the end of the payment year, and, in the case of a qualifying EP who furnishes covered professional services in more than one practice, are determined based on claims submitted for the EP's covered professional services across all such practices.

(b) *Limitations on amounts of incentive payments.*

(1) Except as otherwise provided in paragraph (b)(2) and paragraph (c) of this section, the amount of the incentive payment that a qualifying EP can receive for each payment year is limited to the following amounts:

(i) For the first payment year, \$15,000 (or, if the first payment year for such

qualifying eligible professional is 2011 or 2012, \$18,000).

(ii) For the second payment year, \$12,000.

(iii) For the third payment year, \$8,000.

(iv) For the fourth payment year, \$4,000.

(v) For the fifth payment year, \$2,000.

(vi) For any succeeding payment year for such professional, \$0.

(2)(i) If the first payment year for a qualifying eligible professional is 2014, then the amount for a payment year for a qualifying EP is the same as the amount specified for such payment year for a qualifying EP whose first payment year is 2013.

(ii) If the first payment year for a qualifying EP is after 2014, then the applicable amount specified in this paragraph for such professional for such year and any subsequent year must be \$0.

(c) *Increase in incentive payment limit for EPs who predominantly furnish services in a geographic HPSA.* In the case of a qualifying eligible professional who in the year prior to the payment year furnishes more than 50 percent of his or her covered professional services in a geographic HPSA, the annual incentive payment limit determined under paragraph (b) of this section is to be increased by 10 percent.

(d) *Payment adjustment effective in CY 2015 and subsequent years for nonqualifying EPs.*

(1) Subject to paragraph (d)(3) of this section, beginning in 2015, for covered professional services furnished by an EP who is not a qualifying EP or a hospital-based EP for the year, the payment amount for such services is equal the product of the applicable percent specified in paragraph (d)(2) and the Medicare physician fee schedule amount for such services.

(2) *Applicable percent.* Applicable percent is as follows:

(i) For 2015, 99 percent if the eligible professional is not subject to the payment adjustment for an eligible professional who is not a successful electronic prescriber under section 1848(a)(5) of the Act, or 98 percent if the eligible professional is subject to the payment adjustment for an eligible professional who is not a successful electronic prescriber under section 1848(a)(5) of the Act).

(ii) For 2016, 98 percent.

(iii) For 2017 and each subsequent year, 97 percent.

(3) *Significant hardship exception.* The Secretary may, on a case-by-case basis, exempt an EP who is not a qualifying 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. The Secretary's determination to grant an EP an exemption under this paragraph (d)(3) may be renewed on an annual basis, provided that in no case may an EP be granted an exemption under this paragraph (d)(3) for more than 5 years.

§ 495.104 Incentive payments to eligible hospitals.

(a) *General rule.* A qualifying hospital (as defined in this subpart) shall receive the special incentive payment as determined under the formulas described in paragraph (c) of this section for the period specified in paragraph (b) of this section.

(b) *Transition periods.* Subject to the payment formula specified in paragraph (e) of this section, qualifying hospitals may receive incentive payments during transition periods which comprise the following fiscal years:

(1) Hospitals whose first payment year is FY 2011 may receive such payments for FYs 2011 through 2014.

(2) Hospitals whose first payment year is FY 2012 may receive such payments for FYs 2012 through 2015.

(3) Hospitals whose first payment year is FY 2013 may receive such payments for FYs 2013 through 2016.

(4) Hospitals whose first payment year is FY 2014 may receive such payments for FY 2014 through 2016.

(5) Hospitals whose first payment year is FY 2015 may receive such payments for FY 2015 through 2017.

(c) *Payment methodology.* (1) The incentive payment for each payment year is calculated as the product of the following:

(i) The initial amount determined under paragraph (c)(3) of this section;

(ii) The Medicare share fraction determined under paragraph (c)(4) of this section; and

(iii) The transition factor determined under paragraph (c)(5) of this section.

(2) *Interim and final payments.* CMS uses data on hospital discharges (as that term is defined in § 412.4(a) of this chapter), Medicare Part A inpatient-bed-days, Medicare Part C inpatient-bed-days, and total inpatient-bed-days, from the hospital cost report for the hospital fiscal year that ends during the Federal fiscal year prior to the fiscal year that serves as the payment year as the basis for making preliminary incentive payments. Final payments are determined at the time of settling the hospital cost report for the hospital fiscal year that ends during the payment year, and settled on the basis of data from that cost reporting period.

(3) *Initial amount.* The initial amount is equal to one of the following:

(i) For each hospital with 1,149 discharges or fewer during the fiscal year prior to the payment year, \$2,000,000.

(ii) For each hospital with at least 1,150 but no more 23,000 discharges during the payment year, \$2,000,000 + [\$200 × (n - 1,149)], where n is the number of discharges for the hospital during the fiscal year prior to the payment year.

(iii) For each hospital with more than 23,000 discharges for the fiscal year prior to the payment year, \$6,370,400.

(4) *Medicare share fraction—* (i) *General.* (A) CMS determines the Medicare share fraction by using the number of Medicare Part A, Medicare Part C, and total inpatient-bed-days using data from the Medicare cost report as specified by CMS.

(B) CMS computes the denominator of the Medicare share fraction using the charity care charges reported on the hospital's Medicare cost report.

(ii) The Medicare share fraction is the ratio of—

(A) A numerator which is the sum of—

(1) The number of inpatient-bed-days during the period which are attributable to individuals with respect to whom payment may be made under Part A; and

(2) The number of inpatient-bed-days during the period which are attributable to individuals who are enrolled with a Medicare Advantage organization (as defined in § 422.2 of this chapter).

(iii) A denominator which is the product of—

(A) The total number of inpatient-bed-days during the period; and

(B) The total amount of the eligible hospital's charges during the period, not including any charges that are attributable to charity care divided by the estimated total amount of the hospitals charges during the period.

(5) *Transition factor.* For purposes of the payment formula, the transition factor is as follows:

(i) For hospitals whose first payment year is FY 2011—

(A) 1 for FY 2011;

(B) $\frac{3}{4}$ for FY 2012;

(C) $\frac{1}{2}$ for FY 2013; and

(D) $\frac{1}{4}$ for FY 2014.

(ii) Hospitals whose first payment year is FY 2012—

(A) 1 for FY 2012;

(B) $\frac{3}{4}$ for FY 2013;

(C) $\frac{1}{2}$ for FY 2014; and

(D) $\frac{1}{4}$ for FY 2015;

(iii) Hospitals whose first payment year is FY 2013—

(A) 1 for FY 2013;

(B) $\frac{3}{4}$ for FY 2014;

(C) $\frac{1}{2}$ for FY 2015; and

(D) $\frac{1}{4}$ for FY 2016.

(iv) Hospitals whose first payment year is FY 2014—

(A) $\frac{3}{4}$ for FY 2014;

(B) $\frac{1}{2}$ for FY 2015; and

(C) $\frac{1}{4}$ for FY 2016.

(v) Hospitals whose first payment year is FY 2015—

(A) $\frac{1}{2}$ for FY 2015; and

(B) $\frac{1}{4}$ for FY 2016.

§ 495.106 Incentive payments to CAHs.

(a) *Definitions.* In this section, unless otherwise indicated—

Payment year means a Federal fiscal year beginning after FY 2010 but before FY 2016.

Qualifying CAH means a CAH that would meet the definition of a meaningful EHR user at § 495.4, if it were an eligible hospital.

Reasonable costs incurred for the purchase of certified EHR technology for a qualifying CAH means the reasonable acquisition costs incurred for the purchase of depreciable assets as described in part 413 subpart G of this chapter, such as computers and associated hardware and software, necessary to administer certified EHR technology as defined in § 495.4, excluding any depreciation and interest expenses associated with the acquisition.

(b) *General rule.* A qualifying CAH receives an incentive payment for its reasonable costs incurred for the purchase of certified EHR technology, as defined in paragraph (a) of this section, in the manner described in paragraph (c) of this section for a cost reporting period beginning during a payment year as defined in paragraph (a) of this section.

(c) *Payment methodology—* (1) *Payment amount.* A qualifying CAH receives an incentive payment amount equal to the product of its reasonable costs incurred for the purchase of certified EHR technology and the Medicare share percentage.

(2) *Calculation of reasonable costs.*

CMS or its Medicare contractor computes a qualifying CAH's reasonable costs incurred for the purchase of certified EHR technology, as defined in paragraph (a) of this section, as the sum of—

(i) The reasonable costs incurred for the purchase of certified EHR technology during the cost reporting period that begins in a payment year; and

(ii) Any reasonable costs incurred for the purchase of certified EHR technology in cost reporting periods beginning in years prior to the payment

year which have not been fully depreciated as of the cost reporting period beginning in the payment year.

(3) *Medicare share percentage.* Notwithstanding the percentage applicable under § 413.70(a)(1) of this chapter, the Medicare share percentage equals the lesser of—

(i) 100 percent; or
(ii) The sum of the Medicare share fraction for the CAH as calculated under § 495.104(c)(3) of this subpart and 20 percentage points.

(d) *Incentive payments made to CAHs.* (1) The amount of the incentive payment made to a qualifying CAH under this section represents the expensing and payment of the reasonable costs computed in paragraph (c) of this section in a single payment year and, as specified in § 413.70(a)(5) of this chapter, such payment is made in lieu of payment that would have been made under § 413.70(a)(1) of this chapter for the reasonable costs of the purchase of certified EHR technology including depreciation and interest expenses associated with the acquisition.

(2) The amount of the incentive payment made to a qualifying CAH under this section is paid through a prompt interim payment for the applicable payment year after—

(i) The CAH submits the necessary documentation, as specified by CMS or its Medicare contractors, to support the computation of the incentive payment amount under this section; and

(ii) CMS or its Medicare contractor reviews such documentation and determines the interim amount of the incentive payment.

(3) The interim incentive payment made under this paragraph is subject to a reconciliation process as specified by CMS and the final incentive payment as determined by CMS or its Medicare contractor is considered payment in full for the reasonable costs incurred for the purchase of certified EHR technology in a single payment year.

(4) In no case may an incentive payment be made with respect to a cost reporting period beginning during a payment year before FY 2011 or after FY 2015 and in no case may a CAH receive an incentive payment under this section with respect to more than 4 consecutive payment years.

(e) *Reductions in payment to CAHs.* For cost reporting periods beginning in FY 2015, if a CAH is not a qualifying CAH for a payment year, then the payment for inpatient services furnished by a CAH under § 413.70(a) of this chapter is adjusted by the applicable percentage described in § 413.70(a)(6) of

this chapter unless otherwise exempt from such adjustment.

(f) *Administrative or judicial review.* There is no administrative or judicial review under sections 1869 or 1878 of the Act, or otherwise, of the —

(1) Methodology and standards for determining the amount of payment, the reasonable cost, and adjustments described in this section including selection of periods for determining, and making estimates or using proxies of, inpatient-bed-days, hospital charges, charity charges, and the Medicare share percentage as described in this section;

(2) Methodology and standards for determining if a CAH is a qualified CAH under this section;

(3) Specification of EHR reporting periods, cost reporting periods, payment years, and fiscal years used to compute the CAH incentive payment as specified in this section; and

(4) Identification of the reasonable costs used to compute the CAH incentive payment under paragraph (c) of this section including any reconciliation of the CAH incentive payment amount made under paragraph (d) of this section.

§ 495.108 Posting of required information.

(a) CMS posts, on its Internet Web site, the following information regarding EPs, eligible hospitals, and CAHs receiving an incentive payment under subparts B and C of this part:

(1) Name.

(2) Business addresses.

(3) Business phone number.

(b) CMS posts, on its Internet Web site, the following information for qualifying MA organizations that receive an incentive payment under subpart C of this part—

(1) The information specified in paragraph (a) of this section for each of the qualifying MA organization's MA plan information; and

(2) The information specified in paragraph (a) of this section for each of the qualifying MA organization's MA EPs and MA-affiliated eligible hospitals.

Subpart C—Requirements Specific to Medicare Advantage (MA) Organizations

§ 495.200 Definitions.

As used in this subpart:

First payment year means with respect to—

(1) Covered professional services furnished by a qualifying MA EP, the first calendar year for which an incentive payment is made for such services under this subsection to a qualifying MA organization.

(2) Qualifying MA-affiliated eligible hospitals, the first fiscal year for which

an incentive payment is made for qualifying MA-affiliated eligible hospitals under this subsection to a qualifying MA organization.

Inpatient-bed-days is defined in the same manner and is used in the same manner as that term is defined and used for purposes of implementing section 4201(a) of the American Recovery and Reinvestment Act of 2009 with respect to the Medicare FFS hospital EHR incentive program in § 495.104 of this part.

Patient care services means health care services for which payment would be made under, or for which payment would be based on, the fee schedule established under Medicare Part B if they were furnished by an EP.

Payment year means —

(1) For a qualifying MA EP, a calendar year beginning with CY 2011 and ending with CY 2016; and

(2) For an eligible hospital, a Federal fiscal year beginning with FY 2011 and ending with FY 2016.

Qualifying MA-affiliated eligible hospital means an eligible hospital under section 1886(n)(6) of the Act that is under common corporate governance with a qualifying MA organization and that of the Medicare beneficiaries it serves, more than two-thirds are Medicare individuals enrolled under MA plans, and that is a meaningful user of certified EHR technology as defined by § 495.4 of this part. In the case of a hospital for which at least one-third of whose Medicare bed-days for the year are covered under Part A rather than Part C, payment for that payment year is only be made under section 1886(n) of the Act and not under this section.

Qualifying MA EP means all of the following:

(1) A physician (as described in section 1861(r) of the Act), including a doctor of medicine or osteopathy who is either of the following:

(i) Employed by a qualifying MA organization.

(ii) Employed by, or is a partner of, an entity that through a contract with a qualifying MA organization furnishes at least 80 percent of the entity's Medicare patient care services to enrollees of such organization.

(2) Furnishes at least 80 percent of his or her professional services covered under Title XVIII to enrollees of the qualifying MA organization.

(3) Furnishes, on average, at least 20 hours per week of patient care services to enrollees of the qualifying MA organization during the EHR reporting period.

(4) Is a meaningful user of certified EHR technology in accordance with § 495.4 of this part.

Qualifying MA organization means a MA organization that is organized as a health maintenance organization (HMO) as defined in section 2791(b)(3) of the Public Health Service (PHS) Act which includes a federally qualified HMO, an organization recognized as an HMO under State law, or a similar organization regulated for solvency under State law in the same manner and to the same extent as an HMO.

Second, third, fourth, and fifth payment year means with respect to incentive payments for qualifying—

(1) MA EPs to a qualifying MA organization, each successive calendar year immediately following the first payment year for the qualifying MA organization. The first payment year and each successive year immediately following the first payment year, for the qualifying MA organizations, through 2016, is the same for all qualifying MA EPs with respect to any specific qualifying MA organization.

(2) MA-affiliated eligible hospitals to a qualifying MA organization, each successive fiscal year immediately following the first payment year for the qualifying MA organization.

Under common corporate governance means that a qualifying MA organization and a qualifying MA-affiliated eligible hospital have a common parent corporation, that one is a subsidiary of the other, or that the organization and the hospital have a common board of directors.

§ 495.202 Identification of qualifying MA organizations, MA-EPs and MA-affiliated eligible hospitals.

(a) *Identification of qualifying MA organizations.* (1) Beginning with bids due in June 2010 (for plan year 2011), MA organizations seeking reimbursement for qualifying MA EPs and qualifying MA-affiliated eligible hospitals under the MA EHR incentive program are required to identify themselves to CMS in a form and manner specified by CMS, as part of submissions of initial bids under section 1854(a)(1)(A) of the Act.

(2) Qualifying MA organizations offering MA HMO plans, absent evidence to the contrary, are deemed to meet the definition of HMO in 42 U.S.C. 300gg–91(b)(3)–section 2791(b)(3) of the PHS Act.

(3) Qualifying MA organizations offering MA plan types other than HMOs, must attest to the fact that they meet the definition of HMO in 42 U.S.C. 300gg–91(b)(3)–section 2791(b)(3) of the PHS Act.

(4) Beginning with bids due in June 2014 (for plan year 2015), all MA organizations with potentially

qualifying MA EPs or potentially qualifying MA-affiliated eligible hospitals under the MA EHR incentive program must identify themselves to CMS in a form and manner specified by CMS, as part of submissions of initial bids under section 1854(a)(1)(A) of the Act.

(b) *Identification of qualifying MA EPs and qualifying MA-affiliated eligible hospitals.*

(1) A qualifying MA organization, as part of its initial bid starting with plan year 2011, must make a preliminary identification of potentially qualifying MA EPs and potentially qualifying MA-affiliated eligible hospitals for which the organization is seeking incentive payments.

(2) A qualifying MA organization must provide CMS with the following for each MA EP or eligible hospital:

(i) The MA EP's or MA-affiliated eligible hospital's name.

(ii) The address of the MA EP's practice or MA-affiliated eligible hospital's location.

(iii) NPI.

(iv) An attestation by MA organization specifying that the MA EP or MA-affiliated eligible hospital meets the eligibility criteria.

(3) Final identification of potentially qualifying MA EP or MA-affiliated eligible hospital must be made by the end of the payment year as defined in § 495.200 for which MA EHR incentive payments are being sought.

(4) Beginning plan year 2015 and for subsequent plan years, all qualifying MA organizations, as part of their initial bids in June for the following plan year must—

(i) Identify potentially qualifying MA EPs and potentially qualifying MA-affiliated eligible hospitals;

(ii) Include information specified in paragraph (b)(2)(i)(A) through (C) of this section for each professional and hospital.

(iii) Include an attestation that each professional and hospital either meets or does not meet the EHR incentive payment eligibility criteria.

§ 495.204 Incentive payments to qualifying MA organizations for MA-EPs and hospitals.

(a) *General rule.* A qualifying MA organization receives an incentive payment for its qualifying MA-EPs and its qualifying MA-eligible hospitals. The incentive payment amount paid to a qualifying MA organization for a—

(1) Qualifying MA-EP is the amount determined under paragraph (b) of this section; and

(2) Qualifying MA-eligible hospital is the amount determined under paragraph (c) of this section.

(b) *Amount payable to qualifying MA organization for qualifying MA EPs.*

(1) CMS substitutes an amount determined to be equivalent to the amount computed under § 495.102 of this part.

(2) The qualifying MA organization must report to CMS within 30 days 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.

(3) CMS calculates the incentive amount for the MA organization for each qualifying MA EP as an amount equal to 75 percent of the reported annual revenue specified in paragraph (b)(2) of this section, up to the maximum amounts specified under 1848 (o)(1)(B) of the Act.

(4) For qualifying MA EPs who are compensated on a salaried basis, CMS requires the qualifying MA organization to develop a methodology for estimating the portion of each qualifying MA EP's salary 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 methodology—

(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 salaried qualifying MA EP.

(5) For qualifying MA EPs who are not salaried, qualifying MA organizations must obtain attestations from such qualifying MA EPs as to the amount of compensation received by such EPs for MA plan enrollees of the MA organization. The organizations must submit to CMS compensation information for each such MA EP based on such attestations.

(c) *Amount payable to qualifying MA organization for qualifying MA-affiliated eligible hospitals.*

(1) CMS substitutes an amount determined to be equivalent to the amount computed under § 495.104, to the extent data are not available to compute payments for qualifying MA-affiliated eligible hospitals under the Medicare FFS EHR hospital incentive program. CMS uses the same methodology and defines “inpatient-bed-days” and other terms as used under the Medicare FFS EHR hospital incentive program in § 495.104 of this part in computing amounts due qualifying MA organizations for MA-affiliated eligible hospitals.

(2) To the extent data are available, qualifying MA organizations must receive hospital incentive payments through their affiliated hospitals under the Medicare FFS EHR hospital incentive program, rather than through the MA EHR hospital incentive program.

(d) *Payment to qualifying MA organizations.* CMS makes payment to qualifying MA organizations for qualifying MA EPs only under the MA EHR incentive program and not under the Medicare FFS EHR incentive program to the extent an EP has earned less than the maximum incentive payment for the same period under the Medicare FFS EHR incentive program.

(e) *Payment review under MA.* To ensure the accuracy of the incentive payments, CMS conducts selected compliance reviews of qualifying MA organizations to ensure that EPs and eligible hospitals for which such qualifying organizations received incentive payments were meaningful users of certified EHR technology in accordance with § 422.504 of this chapter.

(1) The reviews include validation of the status of the organization as a qualifying MA organization, verification of meaningful use and review of data used to calculate incentive payments.

(2) MA organizations are required to maintain evidence of their qualification to receive incentive payments and the data necessary to accurately calculate incentive payments.

(3) Documents and records must be maintained for 10 years from the date such payments are made with respect to a given payment year.

(4) Payments that result from incorrect or fraudulent attestations, cost data, or any other submission required to establish eligibility or to qualify for such payment, will be recouped by CMS from the MA organization.

§ 495.206 Timeframe for payment to qualifying MA organizations.

(a) CMS makes payment to qualifying MA organizations for qualifying MA EPs under the MA EHR incentive program after computing incentive payments due under the Medicare FFS EHR incentive program according to § 495.102.

(b) Payments to qualifying MA organizations for qualifying MA-affiliated eligible hospitals under common corporate governance are made under the Medicare FFS EHR incentive program, following the timeline in specified in § 495.104 of this part. To the extent sufficient data do not exist to pay qualifying MA-affiliated eligible hospitals under common corporate governance under the Medicare FFS

EHR incentive program, payment is made under the MA EHR incentive program, following the same timeline in § 495.104 of this part.

§ 495.208 Avoiding duplicate payment.

(a) Unless a qualifying MA EP is entitled to a maximum payment for a year under the Medicare FFS EHR incentive program, payment for such an individual is only be made under the MA EHR incentive program to a qualifying MA organization.

(b) Payment to qualifying MA organizations for a qualifying MA-affiliated eligible hospital under common governance only occurs under the MA EHR incentive program to the extent that sufficient data does not exist to pay such hospital under the Medicare FFS hospital incentive program under § 495.104 of this part. In no event are EHR incentive payments made for a hospital for a payment year under this section to the extent they have been made for the same hospital for the same payment year under § 495.104 of this part.

(c) Each qualifying MA organization must ensure that all potentially qualifying MA EPs are enumerated through the NPI system and that other identifying information required under § 495.210(b) is provided to CMS.

§ 495.210 Meaningful user attestation.

(a) Qualifying MA organizations are required to attest, in a form and manner specified by CMS, that each qualifying MA EP and qualifying MA-affiliated eligible hospitals is a meaningful EHR user.

(b) Qualifying MA organizations are required to attest within 30 days 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 30 days after close of the FY whether each qualifying MA-affiliated eligible hospital is a meaningful user.

§ 495.212 Limitation on review.

(a) There is no administrative or judicial review under section 1869 or 1878 of the Act, or otherwise of the methodology and standards for determining payment amounts and payment adjustments under the MA EHR EP incentive program. This includes provisions related to duplication of payment avoidance and rules developed related to the fixed schedule for application of limitation on incentive payments for all qualifying MA EPs related to a specific qualifying MA organization. It also includes the methodology and standards developed

for determining qualifying MA EPs and the methodology and standards for determining a meaningful EHR user, including the means of demonstrating meaningful use and the selection of measures.

(b) There is no administrative or judicial review under sections 1869 or 1878 of the Act, or otherwise, of the methodology and standards for determining payment amounts and payment adjustments under the MA EHR hospital incentive program. This includes provisions related to duplication of payment avoidance. It also includes the methodology and standards developed for determining qualifying MA-affiliated eligible hospitals and the methodology and standards for determining a meaningful EHR user, including the means of demonstrating meaningful use and the selection of measures.

Subpart D—Requirements Specific to the Medicaid Program

§ 495.300 Basis and purpose.

This subpart implements section 4201 of the American Reinvestment and Recovery Act of 2009 and sections 1903(a)(3)(F) and 1903(t) of the Act which authorizes States, at their option, to provide for incentive payments to Medicaid providers for adopting, implementing, or upgrading certified electronic health record technology or for meaningful use of such technology. This subpart also provides enhanced Federal financial participation (FFP) to States to administer these incentive payments.

§ 495.302 Definitions.

As used in this subpart—

Acceptance documents mean written evidence of satisfactory completion of an approved phase of work or contract and acceptance thereof by the State agency.

Acquisition means to acquire health information technology (HIT) equipment or services for the purpose of implementation and administration under this Part from commercial sources or from State or local government resources.

Acute care hospital means a health care facility—

(1) Where the average length of patient stay is 25 days or fewer; and
(2) With a CMS certification number (previously known as the Medicare provider number) that has the last four digits in the series 0001—0879

Adopt, implement or upgrade means—

(1) Install or commence utilization of certified EHR technology capable of

meeting meaningful use requirements; or

(2) Expand the available functionality of certified EHR technology capable of meeting meaningful use requirements at the practice site, including staffing, maintenance, and training.

Children's hospital means a separately certified children's hospital, either freestanding or hospital-within-hospital that—

(1) Has a CMS certification number, (previously known as the Medicare provider number), that has the last 4 digits in the series 3300–3399; and

(2) Predominantly treats individuals under 21 years of age.

Entities promoting the adoption of certified electronic health record technology means the State-designated entities that are promoting the adoption of certified EHR technology by enabling oversight of the business, operational and legal issues involved in the adoption and implementation of EHR or by enabling the exchange and use of electronic clinical and administrative data between participating providers, in a secure manner, including maintaining the physical and organizational relationship integral to the adoption of certified EHR technology by EPs.

Health information technology planning advance planning document (HIT PAPD) means a plan of action that requests FFP and approval to accomplish the planning necessary for a State agency to determine the need for and plan the acquisition of HIT equipment or services or both and to acquire information necessary to prepare a HIT implementation advanced planning document or request for proposal to implement the State Medicaid HIT plan.

HIT implementation advance planning document (HIT IAPD) means a plan of action that requests FFP and approval to acquire and implement the proposed State Medicaid HIT plan services or equipment or both.

Medicaid information technology architecture (MITA) is both an initiative and a framework. It is a national framework to support improved systems development and health care management for the Medicaid enterprise. It is an initiative to establish national guidelines for technologies and processes that enable improved program administration for the Medicaid enterprise. The MITA initiative includes an architecture framework, models, processes, and planning guidelines for enabling State Medicaid enterprises to meet common objectives with the framework while supporting unique local needs.

Medicaid management information system (MMIS) means a mechanized claims processing and information retrieval system—referred to as Medicaid Management Information Systems (MMIS)—that meets specified requirements and that the Department has found (among other things) is compatible with the claims processing and information retrieval systems used in the administration of the Medicare program. The objectives of the MMIS are to include claims processing and retrieval of utilization and management information necessary for program administration and audit and must coordinate with other mechanized systems and subsystems that perform other functions, such as eligibility determination.

Needy individuals mean individuals that meet one of following:

(1) Received medical assistance from Medicaid or the Children's Health Insurance Program.

(2) Were furnished uncompensated care by the provider.

(3) Were furnished services at either no cost or reduced cost based on a sliding scale determined by the individuals' ability to pay.

Patient volume means the minimum participation threshold where the numerator is the total number of Medicaid patients or needy individuals treated in any 90-day period in the most recent calendar year preceding the reporting and the denominator is all patient encounters in the same 90-day period. Represented as follows:

[Total (Medicaid) treated in any 90-day period in the most recent calendar year preceding the reporting/Total patients in same 90-day period] * 100; or

[Total (Needy Individuals) treated in any 90-day period in the most recent calendar year preceding the reporting/Total patients in same 90-day period] * 100.

Practices predominantly means an EP for whom the clinical location for over 50 percent of his or her total patient encounters over a period of 6 months in the most recent calendar year occurs at a federally qualified health center or rural health clinic.

Service oriented architecture or service component based architecture means organizing and developing information technology capabilities as collaborating services that interact with each other based on open standards.

State Medicaid health information technology plan (SMHP) means a document that describes the State's current and future HIT activities.

State self-assessment means a process that a State uses to review its strategic

goals and objectives, measure its current business processes and capabilities against the (MITA) business capabilities and ultimately develops target capabilities to transform its Medicaid enterprise to be consistent with the MITA principles.

§ 495.304 Medicaid provider scope and eligibility.

(a) *General rule.* The following Medicaid providers are eligible to participate in the HIT incentives program:

(1) Medicaid EPs.

(2) Acute care hospitals.

(3) Children's hospitals.

(b) *Medicaid EP.* The Medicaid professional eligible for a EHR incentive payment is limited to the following:

(1) A physician.

(2) A dentist.

(3) A certified nurse-midwife.

(4) A nurse practitioner.

(5) A physician assistant practicing in a Federally Qualified Health Center or Rural Health Clinic, which is so led by a physician assistant.

(c) *Additional requirements for the Medicaid EP.* To qualify for an EHR incentive payment, a Medicaid EP must not be hospital-based as defined § 495.4 of this subpart and meet one of the following criteria for each year for which the EP seeks an EHR incentive payment:

(1) Have a minimum 30 percent patient volume attributable to individuals receiving Medicaid.

(2) Have a minimum 20 percent patient volume attributable to individuals receiving Medicaid, and be a pediatrician.

(3) Practice predominantly in a FQHC or RHC and have a minimum 30 percent patient volume attributable to needy individuals, as defined at § 495.302.

(d) *Exception.* The hospital-based exclusion in paragraph (c) does not apply to the Medicaid-EP qualifying based on practicing predominantly at a FQHC or RHC.

(e) *Additional requirement for the eligible hospital.* To be eligible for an EHR incentive payment for each year for which the eligible hospital seeks an EHR incentive payment the eligible hospital must meet the following criteria:

(1) An acute care hospital must have at least a 10 percent Medicaid patient volume for each year for which the hospital seeks an EHR incentive payment.

(2) A children's hospital is exempt from meeting a patient volume threshold.

§ 495.306 Establishing patient volume.

(a) A Medicaid provider must annually meet one of the following to establish patient volume:

(1)(i) *General rule for a professional.* Except as specified in paragraph (a)(1)(ii) of this section, a Medicaid EP must attest that a minimum of 30 percent of his or her patient encounters over any continuous 90-day period in the most recent calendar year was covered by Medicaid.

(ii) *Optional exception.* (A) A pediatrician must attest that a minimum of 20 percent of his or her patient encounters over any continuous 90-day period in the most recent calendar year was covered by Medicaid.

(B) A Medicaid EP practicing predominantly in a Federally Qualified Health Center or Rural Health Clinic must attest that a minimum of 30 percent of his or her patient encounters over any continuous 90-day period in the most recent calendar year was with needy individuals as defined in § 495.302 of this subpart.

(2) *General rule for an acute care hospital.* An acute care hospital must attest that a minimum of 10 percent of all patient encounters over any continuous 90-day period in the most recent calendar year was covered by Medicaid.

(b) If a State has an alternative approach to the established timeframe for measuring patient volume, the State must submit the approach to CMS for review and prior approval. CMS determines if it is an acceptable alternative.

(1) To be considered for approval, the alternative approach must be justified and have a verifiable data source.

(2) If CMS approves the State's alternative approach to the established timeframe for measuring patient volume, such timeframe would apply to Medicaid EPs and eligible hospitals, instead of the 90-day timeframe described in paragraph (a) of this section.

(c) To establish patient volume for an EP who practices predominantly in a Federally Qualified Health Center or Rural Health Clinic by use of uncompensated care data, an adjustment to the uncompensated care data must be completed so that it is an appropriate proxy for charity care, including a downward adjustment to eliminate bad debt data from uncompensated care.

(d) An individual enrolled in a managed care organization, pre-paid inpatient health plan, or pre-paid ambulatory health plan under part 438 of this chapter must be included in the calculation to establish patient volume.

§ 495.308 Net average allowable costs as the basis for determining the incentive payment.

(a) *The first year of payment.* (1) The incentive is intended to offset the costs associated with the initial adoption of certified electronic health records technology.

(2) The maximum net average allowable costs for the first year are \$25,000.

(b) *Subsequent payment years.* (1) The incentive is intended to offset maintenance and operation of certified EHR technology.

(2) The maximum net average allowable costs for each subsequent year are \$10,000.

§ 495.310 Medicaid provider incentive payments.

(a) *General rule for a Medicaid EP.* The Medicaid EP's incentive payments are subject to the following limitations:

(1) First payment year. A first year payment may not exceed 85 percent of the maximum threshold of \$25,000, which equals \$21,250.

(2) *Subsequent annual payment years.* A subsequent annual payment may not exceed 85 percent of the maximum threshold of \$10,000, which equals \$8,500.

(i) Payments after the first year may continue for a maximum of 5 years.

(ii) Medicaid EPs may participate for a total of 6 years and may not begin receiving payments any later than CY 2016.

(3) *Maximum incentives.* In no case will the maximum incentive over a 6-year period exceed \$63,750.

(4) *Limitation.* For a Medicaid EP who is a pediatrician described in paragraph (b) of this section is as follows:

(i) The maximum payment in the first year is further reduced to two-thirds, which equals \$14,167.

(ii) The maximum payment in subsequent years is further reduced to two-thirds, which equals \$5,667.

(iii) In no case will the maximum incentive payment to a pediatrician under this limitation exceed \$42,500 over a 6-year period.

(b) *Optional exception for pediatricians.* A pediatrician described in this paragraph is a Medicaid EP who does not meet the 30 percent patient volume requirements described in § 495.304 and § 495.306, but who meets the 20 percent patient volume requirements described in such sections.

(c) *General rule for EPs.* An EP may only receive an incentive payment from either Medicare or Medicaid but not both.

(d) *Optional exception for EPs.* An EP may change his or her EHR incentive

payment program election once, consistent with § 495.10 of this part but such change in election must occur for payments by occurring before CY 2015.

(e) *General rule for Medicaid EPs and hospitals.* An Medicaid EP or hospital may receive an incentive payment from only one State in a payment year.

(f) *Incentive payments to hospitals.* Incentive payments to an eligible hospital under this subpart are subject to all of the following conditions:

(1) The payment is provided over a minimum of a 3-year period and maximum of a 6-year period.

(2) The total incentive payment received over all payment years of the program is not greater than the aggregate EHR incentive amount, as calculated under paragraph (g) of this section.

(3) No single incentive payment for a payment year may exceed 50 percent of the aggregate EHR hospital incentive amount calculated under paragraph (g) of this section for an individual hospital.

(4) No incentive payments over a 2-year period may exceed 90 percent of the aggregate EHR hospital incentive amount calculated under paragraph (g) of this section for an individual hospital.

(5) No hospital may begin receiving incentive payments for any year after 2016.

(6) A multi-site hospital with one CMS Certification Number is considered one hospital for purposes of calculating payment.

(g) *Calculation of the aggregate EHR hospital incentive amount.* The aggregate EHR hospital incentive amount is calculated as the product of the (overall EHR amount) times (the Medicaid Share).

(1) *Overall EHR amount.* The overall EHR amount for an eligible hospital is based upon a theoretical 4 years of payment the hospital would receive based, for each of such 4 years, upon the product of the following:

(i) *Initial amount.* The initial amount is equal to the sum of—

(A) The base amount which is set at \$2,000,000 for each of the theoretical 4 years; plus

(B) The discharge related amount for a 12-month period selected by the State but with the Federal fiscal year before the hospital's fiscal year that serves as the payment year. The discharge related amount is the sum of the following, with discharges over the 12-month period and based upon the total discharges for the eligible hospital (regardless of any source of payment):

(1) For the first through 1,149th discharge, \$0.

(2) For the 1,150th through the 23,000th discharge, \$200.

(3) For any discharge greater than the 23,000th, \$0.

(C) For purposes of calculating the discharge-related amount under paragraph (g)(1)(i)(B) of this section, for the last 3 of the theoretical 4 years of payment, discharges are assumed to increase by the provider's average annual rate of growth for the most recent 3 years for which data are available per year. Negative rates of growth must be applied as such.

(ii) *Medicare share*. The Medicare share, which equals 1.

(iii) *Transition factor*. The transition factor which equals as follows:

(A) For the first of the theoretical 4 years, 1.

(B) For the second of the theoretical 4 years, $\frac{3}{4}$.

(C) For the third of the theoretical 4 years, $\frac{1}{2}$.

(D) For the fourth of the theoretical 4 years, $\frac{1}{4}$.

(2) *Medicaid share*. The Medicaid share specified under this paragraph for an eligible hospital is equal to a fraction—

(i) The numerator of which is the sum (for the 12 month period selected by the State and with respect to the eligible hospital) of—

(A) The estimated number of inpatient-bed-days which are attributable to Medicaid individuals; and

(B) The estimated number of inpatient-bed-days which are attributable to individuals who are enrolled in a managed care organization, a pre-paid inpatient health plan, or a pre-paid ambulatory health plan under part 438 of this chapter; and

(ii) The denominator of which is the product of—

(A) The estimated total number of inpatient-bed-days with respect to the eligible hospital during such period; and

(B) The estimated total amount of the eligible hospital's charges during such period, not including any charges that are attributable to charity care, divided by the estimated total amount of the hospital's charges during such period.

(iii) In computing inpatient-bed-days under the previous sentence, a State may not include estimated inpatient-bed-days attributable to individuals with respect to whom payment may be made under Medicare Part A, or inpatient-bed-days attributable to individuals who are enrolled with a Medicare Advantage organization under Medicare Part C.

(h) *Approximate proxy for charity care*. If the State determines that an

eligible hospital's data are not available on charity care necessary to calculate the portion of the formula specified in paragraph (g)(2)(ii)(B) of this section, the State may use that provider's data on uncompensated care to determine an appropriate proxy for charity care, but must include a downward adjustment to eliminate bad debt from uncompensated care data. The State must use auditable data sources.

(i) *Deeming*. In the absence of the data necessary, with respect to an eligible hospital the amount described in paragraph (g)(2)(ii)(B) must be deemed to be 1. In the absence of data, with respect to an eligible hospital, necessary to compute the amount described in paragraph (g)(2)(i)(B) of this section, the amount under such clause must be deemed to be 0.

(j) *Dual eligibility for incentives payments*. A hospital may receive incentive payments from both Medicare and Medicaid if it meets all eligibility criteria.

(k) *Payments to State-designated entities*. Payments to entities promoting the adoption of certified EHR technology as designated by the State must meet the following requirements:

(1) A Medicaid EP may designate his or her incentive payment to an entity promoting the adoption of certified EHR technology, as defined in § 495.302, and as designated by the State, only under the following conditions:

(i) The State has established a method to designate entities promoting the adoption of EHR technology that comports with the Federal definition in § 495.302.

(ii) The State publishes and makes available to all EPs a voluntary mechanism for designating annual payments and includes information about the verification mechanism the State will use to ensure that the assignment is voluntary and that no more than 5 percent of the annual payment is retained by the entity for costs not related to certified EHR technology.

(2) [Reserved]

§ 495.312 Process for payments.

(a) *General rule*. States must have a process for making payments consistent with the requirements in subparts A and D of this part.

(b) *Reporting data consistent with this subpart*. In order to receive a payment under this part, a provider must report the required data under subpart A and this subpart within the EHR reporting period described in § 495.4.

(c) *State role*. The State determines the provider's eligibility for the EHR incentive payment under subpart A and

this subpart and approves, processes, and makes timely payments using a process approved by CMS.

(d) *State disbursement*. The State disburses an incentive payment to the provider based on the criteria described in subpart A and this subpart.

(e) *Timeframes*. Payments are disbursed consistent with the following timeframes for each type of Medicaid eligible provider:

(1) *Medicaid EPs*. States disburse payments consistent with the calendar year on a rolling basis following the end of the EHR reporting period for the payment year.

(2) *Medicaid eligible hospitals*. States disburse payments consistent with the Federal fiscal year on a rolling basis following the end of the EHR reporting period for the payment year.

§ 495.314 Activities required to receive an incentive payment.

(a) *First payment year*. (1) In the first payment year, to receive an incentive payment, the Medicaid EP or eligible hospital must meet one of the following:

(i) Demonstrate that during the EHR reporting period for a payment year, it has adopted, implemented, or upgraded certified EHR technology, as defined in § 495.302; or

(ii) Demonstrate that during the EHR reporting period for a payment year, it is a meaningful EHR user as defined in § 495.4.

(2) A provider may notify the State of its non-binding intention to participate in the incentives program prior to having fulfilled all of the eligibility criteria.

(b) *Subsequent payment years*. (1) In the second, third, fourth, fifth, and sixth payment years, to receive an incentive payment, the Medicaid EP or eligible hospital must demonstrate that during the EHR reporting period for the applicable payment year, it is a meaningful EHR user, as defined in § 495.4.

(2) The automated reporting of the clinical quality measures will be accomplished using certified EHR technology interoperable with the system designated by the State to receive the data.

§ 495.316 State monitoring and reporting regarding activities required to receive an incentive payment.

(a) Subject to § 495.332 the State is responsible for tracking and verifying the activities necessary for a Medicaid EP or eligible hospital to receive an incentive payment for each payment year, as described in § 495.314.

(b) Subject to § 495.332, the State must submit a State Medicaid HIT Plan to CMS that includes:

(1) A detailed plan for monitoring, verifying and periodic auditing of the requirements for receiving incentive payments, as described in § 495.314; and

(2) A description of the how the State will collect and report on provider meaningful use of certified EHR technology.

(c) Subject to § 495.332 and § 495.350, the State is required to submit to CMS annual reports on the following:

(1) Provider adoption, implementation, or upgrade of certified EHR technology activities and payments; and

(2) Aggregated, de-identified meaningful use data.

(d)(1) The annual report described in paragraph (c) of this section must include, but is not limited to the following:

(i) The number, type, and practice location(s) of providers who qualified for an incentive payment on the basis of having adopted, implemented, or upgraded certified EHR technology;

(ii) Aggregated data tables representing the provider adoption, implementation, and upgrade of certified EHR technology;

(iii) The number, type, and practice location(s) of providers who qualified for an incentive payment on the basis of meaningful use of certified EHR technology;

(iv) Aggregated data tables representing the provider's clinical quality measures data; and

(v) A description and quantitative data on how its incentive payment program addressed individuals with unique needs such as children.

(2) The State may propose additional, not substitute, measures for meaningful use of certified EHR technology, subject to CMS prior approval.

(e) State failure to submit the required reports to CMS may result in discontinued or disallowed funding.

§ 495.318 State responsibilities for receiving FFP.

In order to be provided FFP under section 1903(a)(3)(F) of the Act, a State must demonstrate to the satisfaction of the Department, that the State is—

(a) Using the funds provided for the purposes of administering incentive payments to providers under this program, including tracking of meaningful use by Medicaid providers of EHR technology;

(b) Conducting adequate oversight of the program, including routine tracking of meaningful use attestations and reporting mechanisms; and

(c) Pursuing initiatives to encourage the adoption of certified EHR

technology to promote health care quality and the exchange of health care information, subject to applicable laws and regulations governing such exchange.

§ 495.320 FFP for payments to Medicaid providers.

Subject to the requirements outlined in this Subpart, FFP is available at 100 percent of State expenditures for payments to Medicaid eligible providers to encourage the adoption and meaningful use of certified EHR technology.

§ 495.322 FFP for reasonable administrative expenses.

Subject to prior approval conditions at § 495.324 of this subpart, FFP is available at 90 percent in State expenditures for administrative activities in support of implementing incentive payments to Medicaid eligible providers.

§ 495.324 Prior approval conditions.

(a) A State must obtain prior written approval as specified in paragraph (b) of this section, when the State plans to initiate planning and implementation activities in support of Medicaid provider incentive payments encouraging the adoption and use of certified EHR technology with proposed Federal financial participation.

(b) To receive 90 percent match, each State must receive prior approval for all of the following:

(1) The HIT planning advance planning document and the implementation advance planning document.

(2) A request for proposal and any contract that a State may utilize to complete activities under this subpart, unless specifically exempted by the Department, prior to release of the request for proposal or prior to execution of a contract.

(3) For contract amendments, unless specifically exempted by the Department, before execution of the contract amendment, involving contract cost increases exceeding \$100,000 or contract time extensions of more than 60 days.

(c) Failure to submit any of the information specified in paragraph (b) of this section to the satisfaction of the Department may result in disapproval or suspension of project funding.

(d) A State must obtain prior written approval from the Department of its justification for a sole source acquisition, when it plans to acquire non-competitively from a nongovernmental source HIT equipment or services, with proposed FFP under

this subpart if the total State and Federal acquisition cost is more than \$100,000.

§ 495.326 Disallowance of Federal financial participation (FFP).

If the Department finds that any acquisition approved or modified under the provisions of this subpart fails to comply with the criteria, requirements, and other undertakings described in the approved HIT planning advance planning document and HIT implementation advance planning document to the detriment of the proper and efficient operation of the Medicaid program, payment of FFP may be disallowed. In the case of a suspension of approval of a HIT planning advance planning document and HIT implementation advance planning document, see 45 CFR 205.37(c) and 307.40(a).

§ 495.328 Request for reconsideration of adverse determination.

If CMS disapproves a State request for any elements of a State's advance planning document or State Medicaid HIT Plan under this subpart, or determines that requirements are met for approval on a date later than the date requested, the decision notice includes the following:

(a) The finding of fact upon which the determination was made.

(b) The procedures for appeal of the determination in the form of a request for reconsideration.

§ 495.330 Termination of Federal financial participation (FFP) for failure to provide access to information.

(a) The Department terminates FFP at any time if the Medicaid agency fails to provide State and Federal representatives with full access to records relating to HIT planning and implementation efforts, and the systems used to interoperate with electronic HIT, including on-site inspection.

(b) The Department may request such access at any time to determine whether the conditions in this subpart are being met.

§ 495.332 State Medicaid (HIT) plan requirements.

Each State Medicaid HIT plan must include all of the following elements:

(a) *State systems.* For State systems, interoperability, and the current and future visions:

(1) A baseline assessment of the current HIT landscape environment in the State including the inventory of existing HIT in the State. The assessment must include a comprehensive—

(i) Description of the HIT “as-is” landscape;

(ii) Description of the HIT “to-be” landscape; and

(iii) HIT roadmap and strategic plan for the next 5 years.

(2) A description of how the State Medicaid HIT plan will be planned, designed, developed and implemented, including how it will be implemented in accordance with the Medicaid Information Technology Architecture (MITA) principles as described in the Medicaid Information Technology Framework 2.0. The MITA initiative—

(i) Establishes national guidelines for technologies and processes that enable improved program administration for the Medicaid enterprise;

(ii) Includes business, information and technology architectures that provide an overall framework for interoperability, as well as processes and planning guidelines for enabling State Medicaid enterprises to meet common objectives within the framework while supporting unique local needs; and

(iii) Is important to the design and development of State EHR incentive payment systems.

(3) A description of how intrastate systems, including the Medicaid Management Information System (MMIS) and other automated mechanized claims processing and information retrieval systems—

(i) Have been considered in developing a HIT solution; and

(ii) A plan that incorporates the design, development, and implementation phases for interoperability of such State systems with a description of how any planned systems enhancements support overall State and Medicaid goals.

(4) A description of data-sharing components of HIT solutions.

(5) A description of how each State will promote secure data exchange, where permissible under the Health Insurance Portability and Accountability Act (HIPAA), HIPAA and other requirements included in the Recovery Act.

(6) A description of how each State will promote the use of data and technical standards to enhance data consistency and data sharing through common data-access mechanisms.

(7) A description of how each State will support integration of clinical and administrative data.

(8) A description of the process in place for ensuring improvements in health outcomes, clinical quality, or efficiency resulting from the adoption of certified EHR technology by recipients of Medicaid incentive payments and a

methodology for verifying such information.

(9) A description of the process in place for ensuring that any certified EHR technology used as the basis for a payment incentive to Medicaid providers is compatible with State or Federal administrative management systems, including the MMIS or other automated claims processing system or information retrieval system and a methodology for verifying such information.

(10) A description of how each State will adopt national data standards for health and data exchange and open standards for technical solutions as they become available.

(11) A description of how the State intends to address the needs of underserved and vulnerable populations such as children, individuals with chronic conditions, Title IV–E foster care children, individuals in long-term care settings and the aged, blind, and disabled. This description must address the following:

(i) Person centered goals and objectives and shared decision-making.

(ii) Coordination of care across multiple service providers, funding sources, settings, and patient conditions.

(iii) Universal design to ensure access by people with disabilities and older Americans.

(iv) Self-direction including budget development and expenditure tracking.

(v) Institutional discharge planning and diversion activities that are tied to community based service availability.

(b) *Eligibility.* For eligibility, a description of the process in place for all of the following:

(1) For ensuring that each EP and eligible hospital meets all provider enrollment eligibility criteria upon enrollment and re-enrollment to the Medicaid EHR payment incentive program.

(2) For ensuring patient volume consistent with the criteria in § 495.304 and § 495.306 for each EP who practices predominantly in a FQHC or RHC and for each Medicaid EP who is a physician, pediatrician, nurse practitioner, certified nurse midwife or dentist and a methodology in place used to verify such information.

(3) For ensuring that the EP is a provider who meets patient volume consistent with the criteria in § 495.304 and a methodology in place used to verify such information.

(4) For ensuring that each Medicaid EP is not hospital-based and a methodology in place used to verify such information.

(5) To ensure that a hospital eligible for incentive payments has demonstrated an average length of stay of 25 days or less and that a methodology for verifying such information is available.

(c) *Monitoring and validation.* For monitoring and validation of information, States must include the following:

(1) A description of the process in place for ensuring that, because of CMS’ and the States’ oversight responsibilities, all provider information for attestations and any information added to the CMS Single Provider Repository including all information related to patient volume, NPI, Tax identification number (TIN), meaningful use, efforts to adopt, implement, or upgrade are all true and accurate and that any concealment or falsification of a material fact related to the attestation may result in prosecution under Federal and State laws and a methodology in place used to verify such information.

(2) A description of the process in place for ensuring that the EP or eligible hospital is eligible to receive an incentive payment consistent with the criteria outlined in § 495.314 and a methodology in place used to verify such information.

(3) A description of the process in place for capturing attestations from each EP or eligible hospital that they have meaningfully used certified EHR technology during the reporting period, and that they have adopted, implemented, or upgraded certified EHR technology during the reporting period and a description of the methodology in place used to verify such information.

(4) A description of the process in place for capturing clinical quality data from each EP or eligible hospital and a description of the methodology in place used to verify such information.

(5) A description of the process in place for monitoring the compliance of providers coming onto the program with different requirements depending upon the year and a methodology for verifying such information.

(6) A list of the specific actions planned to implement the HIT EHR incentive program, including a description and organizational charts for workgroups within State government including external partners.

(7) A description of the process in place to ensure that no amounts higher than 100 percent of FFP will be claimed for reimbursement of expenditures for State payments to Medicaid eligible providers for the certified EHR technology incentive payment program

and a methodology for verifying such information is available.

(8) A description of the process in place to ensure that no amounts higher than 90 percent of FFP will be claimed for administrative expenses in administering the certified EHR technology incentive payment program and a methodology for verifying such information is available.

(9) A description of the process and methodology for ensuring and verifying such information that includes the following:

(i) Amounts received under section 1903(a)(3)(F) of the Act with respect to payments to a Medicaid EP or eligible hospital are paid directly to such provider (or to an employer or facility to which such provider has assigned payments) without any deduction or rebate.

(ii) All assignments to an entity promoting the adoption of certified EHR technology, as designated by the State, are voluntary for the Medicaid EP involved.

(iii) Entities promoting the adoption of certified EHR technology do not retain more than 5 percent of such payments for costs not related to certified EHR technology (and support services including maintenance and training) that is for, or is necessary for the operation of, such technology.

(10) A description of the process in place for ensuring that each Medicaid EP or eligible hospital that collects an EHR payment incentive has collected a payment incentive from only one State even if the provider is licensed to practice in multiple States and a methodology for verifying such information.

(11)(i) A description of the process in place for ensuring that each EEP or eligible hospital that wishes to participate in the EHR incentive payment program will receive a NPI; and

(ii) A description of how the NPI will be used to coordinate with the CMS so that the EP will choose only one program from which to receive the incentive payment and the hospital payments are tracked accordingly.

(12) A description of the process in place for ensuring that each EP or eligible hospital who wishes to participate in the EHR incentive payment program will provide a TIN to the State for purposes of the incentive payment.

(d) *Payments.* Payments must provide descriptions of the following processes that are in place:

(1) The process in place for ensuring that there is no duplication of Medicare and Medicaid incentive payments to

EPs and a methodology for verifying such information.

(2) The process in place to ensure that any existing fiscal relationships with providers to disburse the incentive payments through Medicaid managed care plans does not result in payments that exceed 105 percent of the capitation rate, in order to comply with the Medicaid managed care incentive payment rules at § 438.6(v)(5)(iii) of this chapter and a methodology for verifying such information.

(3) The process in place to ensure that only appropriate funding sources are used to make Medicaid EHR incentive payments and that a methodology for verifying such information is available.

(4) The process in place to ensure that Medicaid EHR incentive payments are made for no more than 6 years and that no EP or eligible hospital begins receiving payments after 2016 and that a methodology for verifying such information is available.

(5) 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 and the yearly maximum allowable payment thresholds and a methodology for verifying such information is available.

(6) The process in place to ensure that all hospital calculations and hospital payment incentives are made consistent with the requirements of this part and a methodology for verifying such information is available.

(7) The process in place to provide for the timely and accurate payment of incentive payments to EPs and eligible hospitals, including the time frame specified by the State to meet the timely payment requirement.

(8) The process in place and a methodology for verifying such information to provide that any monies that have been paid inappropriately as an improper payment or otherwise not in compliance with this subpart will be recouped and FFP will be repaid.

(e) *For combating fraud and abuse and for provider appeals.* (1) A description of the process in place for a provider to appeal consistent with the criteria described in § 495.370 and a methodology for verifying the following related to the EHR incentives payment program:

(i) Incentive payments.

(ii) Provider eligibility determinations.

(iii) Demonstration of efforts to adopt, implement or upgrade and meaningful use eligibility for incentive payments under this part.

(2) A description of the process in place, and a methodology for verifying

such information, to address Federal laws and regulations designed to prevent fraud, waste, and abuse, including, but not limited to applicable provisions of Federal criminal law, the False Claims Act (32 U.S.C. 3729 *et seq.*), and the anti-kickback statute (section 1128B(b) of the Act).

(f) *Optional—proposed alternatives.* A State may choose to propose any of the following, but they must be included as an element in the State Medicaid HIT Plan for review and approval:

(1) An alternative methodology for measuring patient volume, consistent with § 495.306(b).

(2) (i) Additional requirements for qualifying a Medicaid provider as a meaningful user of certified EHR technology consistent with § 495.4 and § 495.316(e) of this part.

(ii) A State may propose additional meaningful use objectives beyond the Federal standards at § 495.6, if they do not require additional functionality beyond that of certified electronic health record technology. See also § 495.316(e).

(3) A plan for early implementation of incentive payments for a provider who adopts, implements, or upgrades certified EHR technology consistent with the § 495.302 and § 495.314.

(i) An approvable plan must include mechanisms for making timely and accurate payments.

(ii) A State will require a provider to attest that they are not receiving a payment in any other State.

§ 495.334 State self-assessment requirements.

Each State must prepare a State self-assessment that meets the following requirements:

(a) List and prioritize the State's goals and objectives for HIT.

(b) Define the State's current business model and map to the Medicaid information technology architecture business process model.

(c) Assess the State's current capabilities.

(d) Determine the State's target capabilities.

§ 495.336 Health information technology planning advance planning document requirements (HIT PAPD).

Each State's HIT PAPD must contain the following:

(a) A statement of need and objective which clearly state the purpose and objectives of the project to be accomplished and the necessity for the project.

(b) A project management plan which addresses the following:

(1) The planning project organization.

(2) Planning activities and deliverables.

(3) State and contractor resource needs.

(4) Planning project procurement activities and schedule.

(c) A specific budget for the planning of the project.

(d) An estimated total project cost and a prospective State and Federal cost distribution, including planning and implementation.

(e) A commitment to submit a HIT implementation advance planning document.

(f) A commitment to conduct and complete activities which will result in the production of the State Medicaid HIT plan that includes conduct of the following activities:

(1) A statewide HIT environmental baseline self-assessment.

(2) An assessment of desired HIT future environment.

(3) Development of benchmarks and transition strategies to move from the current environment to the desired future environment.

(g) A commitment to submit the plan to CMS for approval.

§ 495.338 Health information technology implementation advance planning document requirements (HIT IAPD).

Each State's HIT IAPD must contain the following:

(a) The results of the activities conducted as a result of the HIT planning advance planning document, including the approved state Medicaid HIT plan.

(b) A statement of needs and objectives.

(c) A statement of alternative considerations.

(d) A personnel resource statement indicating availability of qualified and adequate staff, including a project director to accomplish the project objectives.

(e) A detailed description of the nature and scope of the activities to be undertaken and the methods to be used to accomplish the project.

(f) The proposed activity schedule for the project.

(g) A proposed budget including a consideration of all HIT implementation advance planning document activity costs, including but not limited to the following:

(1) The cost to implement and administer incentive payments.

(2) Procurement or acquisition.

(3) State personnel.

(4) Contractor services.

(5) Hardware, software, and licensing.

(6) Equipment and supplies.

(7) Training and outreach.

(8) Travel.

(9) Administrative operations.

(10) Miscellaneous expenses for the project.

(h) An estimate of prospective cost distribution to the various State and Federal funding sources and the proposed procedures for distributing costs.

(i) A detailed payment listing file that—

(1) Is in an electronic format that may be a field delimited ASCII text file, a commonly used spreadsheet file, or a commonly used database file; and

(2) Shows each EP and eligible hospital for which the State will provide for the payment of incentive payments, including the—

(i) Name of the provider;

(ii) National provider identifier of the provider;

(iii) Type of provider as specified in § 495.304;

(iv) Planned annual payment amounts;

(v) Total of planned payment amounts; and

(vi) Calendar year of each planned annual payment amount.

(j) A statement setting forth the security and interface requirements to be employed for all State HIT systems, and related systems, and the system failure and disaster recovery procedures available.

§ 495.340 As-needed HIT PAPD update and as-needed HIT IAPD update requirements.

Each State must submit a HIT PAPD update or a HIT IAPD no later than 60 days after the occurrence of project changes including but not limited to any of the following:

(a) A projected cost increase of \$100,000 or more.

(b) A schedule extension of more than 60 days for major milestones.

(c) A significant change in planning approach or implementation approach, or scope of activities beyond that approved in the HIT planning advance planning document or the HIT implementation advance planning document.

(d) A change in implementation concept or a change to the scope of the project.

(e) A change to the approved cost allocation methodology.

§ 495.342 Annual HIT IAPD requirements.

Each State's annual HIT IAPD is due 60 days from the HIT IAPD approved anniversary date and must contain the following:

(a) A reference to the approved HIT PAPD/IAPD and all approved changes.

(b) A project activity status which reports the status of the past year's

major project tasks and milestones, addressing the degree of completion and tasks/milestones remaining to be completed and discusses past and anticipated problems or delays in meeting target dates in the approved HIT technology PAPD/IAPD and approved changes to it.

(c) A report of all project deliverables completed in the past year and degree of completion for unfinished products.

(d) A project activity schedule for the remainder of the project.

(e) A project expenditure status which consists of a detailed accounting of all expenditures for project development over the past year and an explanation of the differences between projected expenses in the approved HIT PAPD/IAPD and actual expenditures for the past year.

(f) A report of any approved or anticipated changes to the allocation basis in the advance planning document's approved cost methodology.

(g) An updated detailed payment listing file in an electronic format.

§ 495.344 Approval of the State Medicaid HIT plan, the HIT PAPD and update, the HIT IAPD and update, and the annual HIT IAPD.

The Department does not approve any of these documents that do not include all information required under this subpart.

§ 495.346 Access to systems and records.

The State agency must allow the Department access to all records and systems operated by the State in support of this program, including cost records associated with approved administrative funding and incentive payments to Medicaid providers. State records related to contractors employed for the purpose of assisting with implementation or oversight activities or providing assistance, at such intervals as are deemed necessary by the Department to determine whether the conditions for approval are being met and to determine the efficiency, economy, and effectiveness of the program.

§ 495.348 Procurement standards.

(a) *General rule.* Procurements of HIT equipment and services are subject to the following procurement standards in paragraphs (b) through (f) of this section regardless of any conditions for prior approval. These standards—

(1) Include a requirement for maximum practical open and free competition regardless of whether the procurement is formally advertised or negotiated.

(2) Are established to ensure that such materials and services are obtained in a

cost effective manner and in compliance with the provisions of applicable Federal statutes and executive orders.

(3) Apply when the cost of the procurement is treated as a direct cost of an award.

(b) *Grantee responsibilities.* The standards contained in this section do not relieve the Grantee of the contractual responsibilities arising under its contract(s).

(1) The grantee is the responsible authority, without recourse to the Departmental awarding agency, regarding the settlement and satisfaction of all contractual and administrative issues arising out of procurements entered into in support of an award or other agreement. This includes disputes, claims, and protests of award, source evaluation or other matters of a contractual nature.

(2) Matters concerning violation of statute are to be referred to such Federal, State or local authority as may have proper jurisdiction.

(c) *Codes of conduct.* The grantee must maintain written standards of conduct governing the performance of its employees engaged in the award and administration of contracts.

(1) No employee, officer, or agent must participate in the selection, award, or administration of a contract supported by Federal funds if a real or apparent conflict of interest would be involved.

(2) Such a conflict would arise when the employee, officer, or agent, or any member of his or her immediate family, his or her partner, or an organization which employs or is about to employ any of the parties indicated herein, has a financial or other interest in the firm selected for an award.

(3) The officers, employees, and agents of the grantee must neither solicit nor accept gratuities, favors, or anything of monetary value from contractors, or parties to subagreements.

(4) Grantees may set standards for situations in which the financial interest is not substantial or the gift is an unsolicited item of nominal value.

(5) The standards of conduct provide for disciplinary actions to be applied for violations of such standards by officers, employers, or agents of the grantees.

(d) *Competition.* All procurement transactions must be conducted in a manner to provide, to the maximum extent practical, open and free competition.

(1) The grantee must be alert to organizational conflicts of interest as well as noncompetitive practices among contractors that may restrict or eliminate competition or otherwise restrain trade.

(2) In order to ensure objective contractor performance and eliminate unfair competitive advantage, contractors that develop or draft grant applications, or contract specifications, requirements, statements of work, invitations for bids and requests for proposals must be excluded from competing for such procurements.

(3) Awards must be made to the bidder or offeror whose bid or offer is responsive to the solicitation and is most advantageous to the grantee, price, quality, and other factors considered.

(4) Solicitations must clearly set forth all requirements that the bidder or offeror must fulfill in order for the bid or offer to be evaluated by the grantee.

(5) Any and all bids or offers may be rejected when it is in the grantee's interest to do so.

(e) *Procurement procedures.* All grantees must establish written procurement procedures. These procedures must provide, at a minimum, the following:

(1) Grantees avoid purchasing unnecessary items.

(2) When appropriate, an analysis is made of lease and purchase alternatives to determine which would be the most economical and practical procurement for the grantee and the Federal government.

(3) Solicitations for goods and services provide for all of the following:

(i) A clear and accurate description of the technical requirements for the material, product or service to be procured. In competitive procurements, such a description must not contain features which unduly restrict competition.

(ii) Requirements which the bidder or offer must fulfill and all other factors to be used in evaluating bids or proposals.

(iii) A description, whenever practicable, of technical requirements in terms of functions to be performed or performance required, including the range of acceptable characteristics or minimum acceptable standards.

(iv) The specific features of brand name or equal descriptions that bidders are required to meet when such items are included in the solicitation.

(v) The acceptance, to the extent practicable and economically feasible, of products and services dimensioned in the metric system of measurement.

(vi) Preference, to the extent practicable and economically feasible, for products and services that conserve natural resources and protect the environment and are energy efficient.

(4) Positive efforts must be made by grantees to utilize small businesses, minority-owned firms, and women's business enterprises, whenever possible.

Grantees of Departmental awards must take all of the following steps to further this goal:

(i) Ensure that small businesses, minority-owned firms, and women's business enterprises are used to the fullest extent practicable.

(ii) Make information on forthcoming opportunities available and arrange time frames for purchases and contracts to encourage and facilitate participation by small businesses, minority-owned firms, and women's business enterprises.

(iii) Consider in the contract process whether firms competing for larger contracts intend to subcontract with small businesses, minority-owned firms, and women's business enterprises.

(iv) Encourage contracting with consortia of small businesses, minority-owned firms and women's business enterprises when a contract is too large for one of these firms to handle individually.

(v) Use the services and assistance, as appropriate, of such organizations as the Small Business Administration and the Department of Commerce's Minority Business Development Agency in the solicitation and utilization of small businesses, minority-owned firms and women's business enterprises.

(5) The type of procuring instruments used (for example, fixed price contracts, cost reimbursable contracts, purchase orders, and incentive contracts) must be determined by the grantee but must be appropriate for the particular procurement and for promoting the best interest of the program or project involved.

(6) The "cost-plus-a-percentage-of-cost" or "percentage of construction cost" methods of contracting must not be used.

(7) Contracts must be made only with responsible contractors who possess the potential ability to perform successfully under the terms and conditions of the proposed procurement.

(8) Consideration must be given to such matters as contractor integrity, record of past performance, financial and technical resources or accessibility to other necessary resources.

(9) In certain circumstances, contracts with certain parties are restricted by agencies' implementation of Executive Orders 12549 and 12689, "Debarment and Suspension" as described in 45 CFR part 76.

(10) Some form of cost or price analysis must be made and documented in the procurement files in connection with every procurement action.

(11) Price analysis may be accomplished in various ways, including the comparison of price quotations submitted, market prices,

and similar indicia, together with discounts.

(12) Cost analysis is the review and evaluation of each element of cost to determine reasonableness, allocability, and allowability.

(13) Procurement records and files for purchases in excess of the simplified acquisition threshold must include the following at a minimum:

(i) Basis for contractor selection.

(ii) Justification for lack of competition when competitive bids or offers are not obtained.

(iii) Basis for award cost or price.

(f) *Contract administration.* A system for contract administration must be maintained to ensure contractor conformance with the terms, conditions and specifications of the contract and to ensure adequate and timely follow-up of all purchases. Grantees must evaluate contractor performance and document, as appropriate, whether contractors have met the terms, conditions, and specifications of the contract.

(g) *Additional contract requirements.* The grantee must include, in addition to provisions to define a sound and complete agreement, the following provisions in all contracts, which must also be applied to subcontracts:

(1) Contracts in excess of the simplified acquisition threshold must contain contractual provisions or conditions that allow for administrative, contractual, or legal remedies in instances in which a contractor violates or breaches the contract terms, and provide for such remedial actions as may be appropriate.

(2) All contracts in excess of the simplified acquisition threshold (currently \$100,000) must contain suitable provisions for termination by the grantee, including the manner by which termination must be effected and the basis for settlement.

(h) *Conditions for default or termination.* Such contracts must describe conditions under which the contract may be terminated for default as well as conditions where the contract may be terminated because of circumstances beyond the control of the contractor.

(i) *Access to contract materials and staff.* All negotiated contracts (except those for less than the simplified acquisition threshold) awarded by grantees must include a provision to the effect that the grantee, the Departmental awarding agency, the U.S. Comptroller General, or any of their duly authorized representatives, must have access to any books, documents, papers and records and staff of the contractor which are directly pertinent to a specific program for the purpose of making audits,

examinations, excerpts and transcriptions.

§ 495.350 State Medicaid agency attestations.

(a) The State must provide assurances to the Department that amounts received with respect to sums expended that are attributable to payments to a Medicaid provider for the adoption of EHR are paid directly to such provider, or to an employer or facility to which such provider has assigned payments, without any deduction or rebate.

(b) State Medicaid agency attestations must be provided in accordance with § 433.74 of this chapter.

§ 495.352 Reporting requirements.

Each State must submit to the Department on a quarterly basis a progress report documenting specific implementation and oversight activities performed during the quarter, including progress in implementing the State's approved Medicaid HIT plan.

§ 495.354 Rules for charging equipment.

Equipment acquired under this subpart is subject to the public assistance program requirements concerning the computation of claims for Federal financial participation in accordance with the provisions of 45 CFR part 95, subpart G.

§ 495.356 Nondiscrimination requirements.

State agencies and any other recipients or subrecipients of Federal financial assistance provided under this subpart are subject to the nondiscrimination requirements in 45 CFR parts 80, 84, and 91.

(a) These regulations in 45 CFR parts 80, 84, and 91 prohibit individuals from being excluded from participation in, being denied the benefits of, or being otherwise subjected to discrimination under any program or activity which received Federal financial assistance.

(b) Specifically, 45 part 80 prohibits discrimination on the basis of race, color, or national origin; 45 CFR part 84 prohibits discrimination on the basis of disability; and 45 CFR part 91 prohibits discrimination on the basis of age.

§ 495.358 Cost allocation plans.

State agencies that acquire HIT equipment and services under this subpart are subject to cost allocation plan requirements in 45 CFR part 95.

§ 495.360 Software and ownership rights.

(a) *General rule.* The State or local government must include a clause in all procurement instruments that provides that the State or local government will have all ownership rights in software or

modifications thereof and associated documentation designed, developed or installed with FFP under this Subpart.

(b) *Federal license.* The Department reserves a royalty-free, nonexclusive, and irrevocable license to reproduce, publish, or otherwise use and to authorize others to use for Federal government purposes, such software, modifications, and documentation.

(c) *Proprietary software.* Proprietary operating/vendor software packages such as software that is owned and licensed for use by third parties, which are provided at established catalog or market prices and sold or leased to the general public must not be subject to the ownership provisions in paragraphs (a) and (b) of this section.

(d) *Limitation.* Federal financial participation is not available for proprietary applications software developed specifically for the public assistance programs covered under this subpart.

§ 495.362 Retroactive approval of FFP with an effective date of February 18, 2009.

For administrative activities performed by a State, without obtaining prior approval, which are in support of planning for incentive payments to providers, a State may request consideration of FFP by recorded request in a HIT advance planning document or implementation advance planning document update. In such a consideration, the agency takes into consideration overall Federal interests which may include any of the following:

(a) The acquisition must not be before February 18, 2009.

(b) The acquisition must be reasonable, useful, and necessary.

(c) The acquisition must be attributable to payments for reasonable administrative expenses under section 1903(a)(3)(F)(ii) of the Act.

§ 495.364 Review and assessment of administrative activities and expenses of Medicaid provider health information technology adoption and operation.

(a) CMS conducts periodic reviews on an as needed basis to assess the State's progress described in its approved HIT planning advance planning document and health information technology implementation advance planning document.

(b) During planning, development, and implementation, these reviews will generally be limited to the overall progress, work performance, expenditure reports, project deliverables and supporting documentation.

(c) CMS assesses the State's overall compliance with the approved advance planning document and provide

technical assistance and information sharing from other State projects.

(d) CMS will, on a continuing basis, review, assess and inspect the planning, design, development, implementation, and operation of activities and payments for reasonable administrative expenses related to the administration of payment for Medicaid provider HIT adoption and operation payments to determine the extent to which such activities meet the following:

(1) All requirements of this subpart.

(2) The goals and objectives stated in the approved HIT implementation advance planning document and State Medicaid HIT plan.

(3) The schedule, budget, and other conditions of the approved HIT implementation advance planning document and State Medicaid HIT plan.

§ 495.366 Financial oversight and monitoring of expenditures.

(a) *General rule.* (1) The State must have a process in place to estimate expenditures for the Medicaid EHR payment incentive program using the Medicaid Budget Expenditure System.

(2) The State must have a process in place to report actual expenditures for the Medicaid EHR payment incentive program using the Medicaid Budget Expenditure System.

(3) The State must have an automated payment and information retrieval mechanized system (Medicaid Management Information System) to make EHR payment incentives, to ensure Medicaid provider eligibility, to ensure the accuracy of payment incentives, and to identify potential improper payments.

(b) *Provider eligibility as basis for making payment.* Subject to § 495.332, the State must do all of the following:

(1) Collect and verify basic information on Medicaid providers to assure provider enrollment eligibility upon enrollment or re-enrollment to the Medicaid EHR payment incentive program.

(2) Collect and verify basic information on Medicaid providers to assure patient volume.

(3) Collect and verify basic information on Medicaid providers to assure that EPs are not hospital-based including the determination that substantially all health care services are not furnished in a hospital setting, either inpatient or outpatient.

(4) Collect and verify basic information on Medicaid providers to assure that EPs are practicing predominantly in a Federally qualified health center or rural health clinic.

(5) Have a process in place to assure that Medicaid providers who wish to

participate in the EHR incentive payment program has or will have a NPI and will choose only one program from which to receive the incentive payment using the NPI, a TIN, and CMS' national provider election database.

(c) *Meaningful use and efforts to adopt, implement, or upgrade to certified electronic health record technology to make payment.* Subject to §§ 495.354 and 495.374, the State must annually collect and verify information regarding the efforts to adopt, implement, or upgrade certified EHR technology and the meaningful use of said technology before making any payments to providers.

(d) *Claiming Federal reimbursement for State expenditures.* Subject to § 495.332, the State must do the following:

(1) Assure that State expenditures are claimed in accordance with, including but not limited to, applicable Federal laws, regulations, and policy guidance.

(2) Have a process in place to assure that expenditures for administering the Medicaid EHR incentive payment program will not be claimed at amounts higher than 90 percent of the cost of such administration.

(3) Have a process in place to assure that expenditures for payment of Medicaid EHR incentive payments will not be claimed at amounts higher than 100 percent of the cost of such payments to Medicaid providers.

(e) *Improper Medicaid electronic health record payment incentives.*

(1) Subject to § 495.332, the State must have a process in place to assure that no duplicate Medicaid EHR payment incentives are paid between the Medicare and Medicaid programs, or paid by more than one State even if the provider is licensed to practice in multiple States, or paid within more than one area of a State.

(2) Subject to § 495.332, the State must have a process in place to assure that Medicaid EHR incentive payments are made without reduction or rebate, have been paid directly to an eligible provider or to an employer, a facility, or an eligible third-party entity to which the Medicaid eligible provider has assigned payments.

(3) Subject to § 495.332, the State must have a process in place to assure that Medicaid EHR incentive payments are made for no more than 6 years or for any year starting after the year of 2015 unless the provider has been provided payment under paragraph (b)(1) of this section for the previous year.

(4) Subject to § 495.332, the State must have a process in place to assure that only appropriate funding sources

are used to make Medicaid EHR incentive payments.

(5) Subject to § 495.332, the State must have a process in place to assure that Medicaid EHR incentive payments are not paid at amounts higher than 85 percent of the net average allowable cost of certified EHR technology and the yearly maximum allowable payment thresholds.

(6) Subject to § 495.332, the State must have a process in place to assure that for those entities promoting the adoption of EHR technology, the Medicaid EHR incentive payments are paid on a voluntary basis and that these entities do not retain more than 5 percent of such payments for costs not related to certified EHR technology.

(7) Subject to § 495.332, the State must have a process in place to assure that any existing fiscal relationships with providers to disburse the incentive through Medicaid managed care plans does not exceed 105 percent of the capitation rate, in order to comply with the Medicaid managed care incentive payment rules at § 438.6(c)(5)(iii) of this chapter and a methodology for verifying such information.

(8) The State must not request reimbursement for Federal financial participation unless all requirements of this subpart have been satisfied.

§ 495.368 Combating fraud and abuse.

(a) *General rule.* (1) The State must comply with Federal requirements to—

(i) Ensure the qualifications of the providers who request Medicaid EHR incentive payments;

(ii) Detect improper payments; and

(iii) In accordance with 42 CFR § 455.15 and § 455.21, refer suspected cases of fraud and abuse to the Medicaid Fraud Control Unit.

(2) The State must take corrective action in the case of improper EHR payment incentives to Medicaid providers.

(b) *Providers' statements regarding submission of documentation containing falsification or concealment of a material fact on EHR incentive payment documentation.* On any forms on which a provider submits information necessary to the determination of eligibility to receive EHR incentive payments, the State must obtain the statement that meet the following:

(1) Is signed by the provider and contains the following statement: "This is to certify that the foregoing information is true, accurate, and complete. I understand that Medicaid EHR incentive payments submitted under this provider number will be from

Federal funds, and that any falsification, or concealment of a material fact may be prosecuted under Federal and State laws.”

(2) Appears directly above the claimant’s signature, or if it is printed on the reverse of the form, a reference to the statements must appear immediately preceding the provider’s signature.

(3) Is resubmitted upon a change in provider representative.

(4) Is updated as needed.

(c) *Overpayments.* States must repay to CMS all Federal financial participation received by providers identified as an overpayment regardless of recoupment from such providers, within 60 days of discovery of the overpayment, in accordance with sections 1903(a)(1), (d)(2), and (d)(3) of the Act and part 433 Subpart F of the regulations.

(d) *Complying with Federal laws and regulations.* States must comply with all Federal laws and regulations designed to prevent fraud, waste, and abuse, including, but not limited to applicable

provisions of Federal criminal law, the False Claims Act (32 U.S.C. 3729 *et seq.*), and the anti-kickback statute (section 1128B(b) of the Act).

§ 495.370 Appeals process for a Medicaid provider receiving electronic health record incentive payments.

(a) The State must have a process in place consistent with the requirements established in § 447.253(e) of this chapter for a provider or entity to appeal the following issues related to the HIT incentives payment program:

(1) Incentive payments.

(2) Incentive payment amounts.

(3) Provider eligibility determinations.

(4) Demonstration of adopting, implementing, and upgrading, and meaningful use eligibility for incentives under this subpart.

(b) Subject to paragraph (a) of this section, the State’s process must ensure the following:

(1) That the provider (whether an individual or an entity) has an opportunity to challenge the State’s determination under this Part by

submitting documents or data or both to support the provider’s claim.

(2) That such process employs methods for conducting an appeal that are consistent with the State’s Administrative Procedure law(s).

(c) The State must provide that the provider (whether individual or entity) is also given any additional appeals rights that would otherwise be available under procedures established by the State.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program, Program No. 93.778, Medical Assistance Program.)

Dated: November 13, 2009.

Charlene Frizzera,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: December 28, 2009.

Kathleen Sebelius,

Secretary.

[FR Doc. E9–31217 Filed 12–30–09; 4:15 pm]

BILLING CODE 4120–01–P