

physicians to be called for emergencies, when they can be called, and how they can be reached.

(3) The dialysis facility must have an agreement with a hospital that can provide inpatient care, routine and emergency dialysis and other hospital services, and emergency medical care which is available 24 hours a day, 7 days a week. The agreement must:

(i) Ensure that hospital services are available promptly to the dialysis facility's patients when needed.

(ii) Include reasonable assurances that patients from the dialysis facility are accepted and treated in emergencies.

(h) *Standard: Furnishing data and information for ESRD program administration.* Effective February 1, 2009, the dialysis facility must furnish data and information to CMS and at intervals as specified by the Secretary. This information is used in a national ESRD information system and in compilations relevant to program administration, including claims processing and reimbursement, quality improvement, and performance assessment. The data and information must—

(1) Be submitted at the intervals specified by the Secretary;

(2) Be submitted electronically in the format specified by the Secretary;

(3) Include, but not be limited to—

(i) Cost reports;

(ii) ESRD administrative forms;

(iii) Patient survival information; and

(iv) Existing ESRD clinical performance measures, and any future clinical performance standards developed in accordance with a voluntary consensus standards process identified by the Secretary.

(i) *Standard: Relationship with the ESRD network.* The governing body receives and acts upon recommendations from the ESRD network. The dialysis facility must cooperate with the ESRD network designated for its geographic area, in fulfilling the terms of the Network's current statement of work. Each facility must participate in ESRD network activities and pursue network goals.

(j) *Standard: Disclosure of ownership.* In accordance with §420.200 through §420.206 of this chapter, the governing

body must report ownership interests of 5 percent or more to its State survey agency.

PART 495—STANDARDS FOR THE ELECTRONIC HEALTH RECORD TECHNOLOGY INCENTIVE PROGRAM

Subpart A—General Provisions

Sec.

495.2 Basis and purpose.

495.4 Definitions.

495.5 Requirements for EPs seeking to reverse a hospital-based determination under §495.4.

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, eligible hospitals, and 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.

495.110 Preclusion on administrative and judicial review.

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 qualifying MA-EPs and qualifying MA-affiliated eligible hospitals.

495.206 Timeframe for payment to qualifying MA organizations.

495.208 Avoiding duplicate payment.

495.210 Meaningful EHR user attestation.

495.211 Payment adjustments effective for 2015 and subsequent MA payment years with respect to MA EPs and MA-affiliated eligible hospitals.

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.

§ 495.2

- 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 FFP.
- 495.328 Request for reconsideration of adverse determination.
- 495.330 Termination of FFP for failure to provide access to information.
- 495.332 State Medicaid health information technology (HIT) plan requirements.
- 495.334 Reserved.
- 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).

SOURCE: 75 FR 44565, July 28, 2010, unless otherwise noted.

42 CFR Ch. IV (10–1–15 Edition)

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 eligible professionals who adopt and meaningfully use certified electronic health record (EHR) technology.

(b) Section 1853(1) of the Act to provide incentive payments to Medicare Advantage organizations for certain 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 the Medicare FFS program.

(d) Section 1814(l) of the Act to provide an incentive payment to critical access hospitals that 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(1)(4), 1886(b)(3)(B)(ix)(I), 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 EHR technology, and for covered professional services furnished on or after January 1, 2015 to Medicare beneficiaries by certain professionals who are not meaningful users of certified EHR technology.

§ 495.4 Definitions.

In this part, unless otherwise indicated—

Certified electronic health record technology has the same definition as this term is defined at 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. Except with respect to payment adjustment years, EHR reporting period means either of the following:

(1) For an eligible EP—

(i) For the payment year in which the EP is first demonstrating he or she is a meaningful EHR user, any continuous 90-day period within the calendar year;

(ii) Except as specified in paragraphs (1)(iii) and (1)(iv) of this definition, for the subsequent payment years following the payment year in which the EP first successfully demonstrates he or she is a meaningful EHR user, the calendar year.

(iii) For an EP seeking to demonstrate he or she is a meaningful EHR user for the Medicare EHR incentive program for CY 2014, any of the following 3-month periods:

(A) January 1, 2014 through March 31, 2014.

(B) April 1, 2014 through June 30, 2014.

(C) July 1, 2014 through September 30, 2014.

(D) October 1, 2014 through December 31, 2014.

(iv) For an EP seeking to demonstrate he or she is a meaningful EHR user for the Medicaid EHR incentive program for CY 2014 any continuous 90-day period within CY 2014.

(2) For an eligible hospital or CAH—

(i) For the payment year in which the eligible hospital or CAH is first demonstrating it is a meaningful EHR user, any continuous 90-day period within the Federal fiscal year;

(ii) Except as specified in paragraph (2)(iii) of this definition, for the subsequent payment years following the payment year in which the eligible hospital or CAH first successfully dem-

onstrates it is a meaningful EHR user, the Federal fiscal year.

(iii) For an eligible hospital or CAH seeking to demonstrate it is a meaningful EHR user for FY 2014, any of the following 3-month periods:

(A) October 1, 2013 through December 31, 2013.

(B) January 1, 2014 through March 31, 2014.

(C) April 1, 2014 through June 30, 2014.

(D) July 1, 2014 through September 30, 2014.

EHR reporting period for a payment adjustment year. For a payment adjustment year, the EHR reporting period means the following:

(1) For an EP—

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

(B) The special EHR reporting period for CY 2014 (specified in paragraph (1)(iii) or (1)(iv) of this definition, as applicable) of the definition of “EHR Reporting Period” that occurs within the calendar year that is 2 years before the payment adjustment year and is only for EHR reporting periods in CY 2014.

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

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

(B) Under this exception, the provider must successfully register for and attest to meaningful use no later than the date October 1 of the year before the payment adjustment year.

(2) For an eligible hospital—

(i)(A) Except as provided in paragraphs (2)(i)(B), (ii), and (iii) of this definition, the Federal fiscal year that

§ 495.4

42 CFR Ch. IV (10–1–15 Edition)

is 2 years before the payment adjustment year.

(B) The special EHR reporting period for FY 2014 (defined in paragraph (2)(iii) of the definition “EHR Reporting Period”) that occurs within the fiscal year that is 2 years before the payment adjustment year and is only for EHR reporting periods in fiscal year 2014.

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

(iii)(A) If in the Federal fiscal year that is 2 years before the payment adjustment year and for all prior Federal fiscal years the eligible hospital has not successfully demonstrated it is a meaningful EHR user, then any continuous 90-day period that both begins in the Federal fiscal year that is 1 year before the payment adjustment year and ends at least 3 months before the end of such prior Federal fiscal year.

(B) Under this exception, the eligible hospital must successfully register for and attest to meaningful use no later than July 1 of the year before the payment adjustment year.

(3) For a CAH—

(i) Except as provided in paragraph (3)(ii) of this definition, the Federal fiscal year that is the payment adjustment year.

(ii) If the CAH is demonstrating it is a meaningful EHR user for the first time in the payment adjustment year, any continuous 90-day period within the Federal fiscal year that is the payment adjustment year.

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.

First, second, third, fourth, fifth, or sixth payment years mean as follows:

(1) The first payment year is: with respect to an EP, the first calendar year for which the EP receives an incentive payment under this part; and with respect to an eligible hospital or CAH, the first FY for which the hospital re-

ceives an incentive payment under this part.

(2) The second, third, fourth, fifth, or sixth payment year is:

(i) With respect to a Medicare EP, the second, third, fourth or fifth successive CY immediately following the first payment year; and with respect to a Medicare eligible hospital or CAH, the second, third, or fourth successive Federal FY immediately following the first payment year. (Note: Medicare EPs are not eligible for a sixth payment year and Medicare eligible hospitals are not eligible for a fifth or sixth payment year.)

(ii)(A) With respect to a Medicaid EP, the second, third, fourth, fifth, or sixth CY for which the EP receives an incentive payment under subpart D, regardless of whether the year immediately follows the prior payment year; and

(B) With respect to a Medicaid eligible hospital, for years prior to FY 2017, the second, third, fourth, fifth, or sixth Federal FY for which the hospital receives an incentive payment under subpart D of this part, regardless of whether the year immediately follows the prior payment year. Beginning with FY 2017, payments to Medicaid eligible hospitals must be consecutive, and the hospital is not eligible for an incentive payment under subpart D of this part unless it received such incentive payment for the prior fiscal year.

Hospital-based EP. Unless it meets the requirements of § 495.5, a hospital-based EP means an EP who furnishes 90 percent or more of his or her covered professional services in sites of service identified by the codes used in the HIPAA standard transaction as an inpatient hospital or emergency room setting in the year preceding the payment year, or in the case of a payment adjustment year, in either of the 2 years before the year preceding such payment adjustment year.

(1) For Medicare, this is calculated based on—

(i) The Federal fiscal year preceding the payment year; and

(ii) For the payment adjustments, based on—

(A) The Federal fiscal year 2 years before the payment adjustment year; or

(B) The Federal fiscal year 3 years before the payment adjustment year.

(2) For Medicaid, it is at the State's discretion if the data are gathered on the Federal fiscal year or calendar year preceding the payment year.

(3) For the CY 2013 payment year only, an EP who furnishes services billed by a CAH receiving payment under Method II (as described in § 413.70(b)(3) of this chapter) is considered to be hospital-based if 90 percent or more of his or her covered professional services are furnished in sites of service identified by the codes used in the HIPAA standard transaction as an inpatient hospital or emergency room setting in each of the Federal fiscal years 2012 and 2013.

Meaningful EHR user means:

(1) Subject to paragraph (3) of this definition, an EP, eligible hospital or CAH that, for an EHR reporting period for a payment year or payment adjustment year, demonstrates in accordance with § 495.8 meaningful use of Certified EHR Technology by meeting the applicable objectives and associated measures under § 495.6 and successfully reporting the clinical quality measures selected by CMS to CMS or the States, as applicable, in the form and manner specified by CMS or the States, as applicable; and

(2)(i) Except as specified in paragraph (2)(ii) of this definition, a Medicaid EP or Medicaid eligible hospital, that meets the requirements of 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.

(ii) An eligible hospital or CAH is deemed to be a meaningful EHR user for purposes of receiving an incentive payment under subpart D of this part, if the hospital participates in both the Medicare and Medicaid EHR incentive programs, and the hospital meets the requirements of paragraph (1) of this definition.

(3) To be considered a meaningful EHR user, at least 50 percent of an EP's patient encounters during an EHR reporting period for a payment year (or, in the case of a payment adjustment year, during an applicable EHR reporting period for such payment adjustment year) must occur at a practice/lo-

cation or practices/locations equipped with Certified EHR Technology.

Payment adjustment year means either of the following:

(1) For an EP, a calendar year beginning with CY 2015.

(2) For a CAH or an eligible hospital, a Federal fiscal year beginning with FY 2015.

Payment year means:

(1) For an EP, a calendar year beginning with CY 2011; and

(2) For a CAH or an eligible hospital, a Federal fiscal year beginning with FY 2011.

Qualified EHR has the same definition as this term is defined at 45 CFR 170.102.

[75 FR 44565, July 28, 2010, as amended at 77 FR 54148, Sept. 4, 2012; 78 FR 75200, Dec. 10, 2013]

§ 495.5 Requirements for EPs seeking to reverse a hospital-based determination under § 495.4.

(a) *Exception for certain EPs.* Beginning with payment year 2013, an EP who meets the definition of hospital-based EP specified in § 495.4 but who can demonstrate to CMS that the EP funds the acquisition, implementation, and maintenance of Certified EHR Technology, including supporting hardware and interfaces needed for meaningful use without reimbursement from an eligible hospital or CAH, and uses such Certified EHR Technology in the inpatient or emergency department of a hospital (instead of the hospital's Certified EHR Technology), may be determined by CMS to be a nonhospital-based EP.

(b) *Process for determining a nonhospital-based EP.* When an EP registers for a given payment year they should receive a determination of whether they have been determined "hospital-based."

(1) An EP determined "hospital-based," but who wishes to be determined nonhospital-based as specified in paragraph (a) of section, may use an administrative process to provide documentation and seek a nonhospital-based determination. Such administrative process will be available throughout the incentive payment year and including the 2 months following the incentive payment year in which the EP

§ 495.6

42 CFR Ch. IV (10–1–15 Edition)

may attest to being a meaningful EHR user.

(2) If an EP is determined nonhospital-based under paragraph (a) of this section, to be considered nonhospital-based for subsequent payment years, the EP must attest in such payment year (or by the time the EP must attest it is a meaningful EHR user for such year) that the EP continues to meet the criteria of paragraph (a) of this section.

(c) *Requirements for nonhospital-based EPs.* An EP determined nonhospital-based must—

(1) Continue to meet all applicable requirements to receive an incentive payment, including meeting all requirements for meaningful use; and

(2) Demonstrate meaningful use using all encounters at all locations equipped with Certified EHR Technology, including those in the inpatient and emergency departments of the hospital.

[77 FR 54149, Sept. 4, 2012]

§ 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 paragraphs (a)(2) and (a)(3) of this section, EPs must meet all objectives and associated measures of the Stage 1 criteria specified in paragraph (d) of this section and five objectives of the EP's choice from paragraph (e) of this section to meet the definition of a meaningful EHR user.

(2) *Exclusion for non-applicable objectives.* (i) An EP may exclude a particular objective contained in paragraphs (d) or (e) of this section, if the EP meets all of the following requirements:

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

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

(C) Attests.

(ii) (A) An exclusion will reduce (by the number of exclusions applicable) the number of objectives that would otherwise apply. For example, an EP

that has an exclusion from one of the objectives in paragraph (e) of this section must meet four (and not five) objectives of the EP's choice from such paragraph to meet the definition of a meaningful EHR user.

(B) Beginning 2014, an exclusion does not reduce (by the number of exclusions applicable) the number of objectives that would otherwise apply in paragraph (e) of this section unless five or more objectives can be excluded. An EP must meet five of the objectives and associated measures specified in paragraph (e) of this section, one of which must be either paragraph (e)(9) or (10) of this section, unless the EP has an exclusion from five or more objectives specified in paragraph (e) of this section, in which case the EP must meet all remaining objectives and associated measures in paragraph (e) of this section.

(3) *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 (d) and (e) apply beginning with the second payment year, and do not apply to the first payment year.

(4) *Flexible options for using certified EHR technology in 2014.* For an EHR reporting period in 2014, if an EP could not fully implement 2014 Edition certified EHR technology due to delays in availability and uses—

(i) Only 2011 Edition certified EHR technology, the EP must satisfy the objectives and associated measures of the Stage 1 criteria that were applicable for 2013; or

(ii) A combination of 2011 Edition certified EHR technology and 2014 Edition certified EHR technology, the EP may choose to satisfy one of the following sets of objectives and associated measures:

(A) The Stage 1 criteria that were applicable for 2013.

(B) The Stage 1 criteria that are applicable beginning 2014.

(C) If the EP is scheduled to begin Stage 2 in 2014, the Stage 2 criteria.

(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 paragraphs (b)(2) and (b)(3) of this section, eligible hospitals and CAHs must meet all objectives and associated measures of the Stage 1 criteria specified in paragraph (f) of this section and five objectives of the eligible hospital's or CAH's choice from paragraph (g) of this section to meet the definition of a meaningful EHR user.

(2) *Exclusions for nonapplicable objectives.* (i) An eligible hospital or CAH may exclude a particular objective that includes an option for exclusion contained in paragraphs (f) or (g) of this section, if the hospital meets all of the following requirements:

(A) The hospital meets the criteria in the applicable objective that would permit an exclusion.

(B) The hospital so attests.

(ii)(A) An exclusion will reduce (by the number of exclusions received) the number of objectives that would otherwise apply. For example, an eligible hospital that is excluded from one of the objectives in paragraph (g) of this section must meet four (and not five) objectives of the hospital's choice from such paragraph to meet the definition of a meaningful EHR user.

(B) Beginning 2014, an exclusion does not reduce (by the number of exclusions applicable) the number of objectives that would otherwise apply in paragraph (g) of this section. Eligible hospitals or CAHs must meet five of the objectives and associated measures specified in paragraph (g) of this section, one which must be specified in paragraph (g)(8), (9), or (10) of this section.

(3) *Exception for Medicaid eligible hospitals that adopt, implement or upgrade in their first payment year.* For Medicaid eligible hospitals that 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 (f) and (g) of this section apply beginning with the second payment year, and do not apply to the first payment year.

(4) *Flexible options for using certified EHR technology in 2014.* For an EHR reporting period in 2014, if an eligible

hospital or CAH could not fully implement 2014 Edition certified EHR technology due to delays in availability and uses—

(i) Only 2011 Edition certified EHR technology, the eligible hospital or CAH must satisfy the objectives and associated measures of the Stage 1 criteria that were applicable for 2013;

(ii) A combination of 2011 Edition certified EHR technology and 2014 Edition certified EHR technology, the eligible hospital or CAH may choose to satisfy one of the following sets of objectives and associated measures:

(A) The Stage 1 criteria that were applicable for 2013.

(B) The Stage 1 criteria that are applicable beginning 2014.

(C) If the eligible hospital or CAH is scheduled to begin Stage 2 in 2014, the Stage 2 criteria.

(c) Many of the objective and associated measures in paragraphs paragraphs (d) through (m) of this section rely on measures that count unique patients or actions.

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

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

(d) *Stage 1 core criteria for EPs.* An EP must satisfy the following objectives and associated measures, except those objectives and associated measures for which an EP qualifies for an exclusion under paragraph (a)(2) of this section specified in this paragraph:

(1)(i) *Objective.* Use computerized provider order entry (CPOE) for medication orders directly entered by any licensed healthcare professional who can enter orders into the medical record

per state, local and professional guidelines.

(ii) *Measure*. (A) Subject to paragraph (c) of this section, more than 30 percent of all unique patients with at least one medication in their medication list seen by the EP have at least one medication order entered using CPOE.

(B) Subject to paragraph (c) of this section, more than 30 percent of medication orders created by the EP during the EHR reporting period are recorded using computerized provider order entry, or the measure specified in paragraph (d)(1)(ii)(A) of this section.

(iii) *Exclusion in accordance with paragraph (a)(2) of this section* Any EP who writes fewer than 100 prescriptions during the EHR reporting period.

(2)(i) *Objective*. Implement drug-drug and drug-allergy interaction checks.

(ii) *Measure*. The EP has enabled this functionality for the entire EHR reporting period.

(3)(i) *Objective*. Maintain an up-to-date problem list of current and active diagnoses.

(ii) *Measure*. More than 80 percent of all unique patients seen by the EP have at least one entry or an indication that no problems are known for the patient recorded as structured data.

(4)(i) *Objective*. Generate and transmit permissible prescriptions electronically (eRx).

(ii) *Measure*. Subject to paragraph (c) of this section, more than 40 percent of all permissible prescriptions written by the EP are transmitted electronically using certified EHR technology.

(iii) *Exclusion in accordance with paragraph (a)(2) of this section* (A) Any EP who writes fewer than 100 prescriptions during the EHR reporting period.

(B) Beginning 2013, any EP who does not have a pharmacy within their organization and there are no pharmacies that accept electronic prescriptions within 10 miles of the EP's practice location at the start of his/her EHR reporting period, or the exclusion specified in (d)(4)(iii)(A) of this section.

(5)(i) *Objective*. Maintain active medication list.

(ii) *Measure*. More than 80 percent of all unique patients seen by the EP have at least one entry (or an indication that the patient is not currently pre-

scribed any medication) recorded as structured data.

(6)(i) *Objective*. Maintain active medication allergy list.

(ii) *Measure*. More than 80 percent of all unique patients seen by the EP have at least one entry (or an indication that the patient has no known medication allergies) recorded as structured data.

(7)(i) *Objective*. Record all of the following demographics:

(A) Preferred language.

(B) Gender.

(C) Race.

(D) Ethnicity.

(E) Date of birth.

(ii) *Measure*. More than 50 percent of all unique patients seen by the EP have demographics recorded as structured data.

(8)(i) *Objective*. Record and chart changes in the following vital signs:

(A) Height.

(B) Weight.

(C) Blood pressure.

(D) Calculate and display body mass index (BMI).

(E)(I) Plot and display growth charts for children 2–20 years, including BMI.

(2) For 2013, plot and display growth charts for patients 0–20 years, including body mass index, or paragraph (d)(8)(i)(E)(I) of this section.

(3) Beginning 2014, plot and display growth charts for patients 0–20 years, including body mass index.

(ii) *Measure*. (A) Subject to paragraph (c) of this section, more than 50 percent of all unique patients age 2 and over seen by the EP, height, weight and blood pressure are recorded as structured data.

(B) For 2013—(I) Subject to paragraph (c) of this section, more than 50 percent of all unique patients seen by the EP during the EHR reporting period have blood pressure (for patients age 3 and over only) and height/length and weight (for all ages) recorded as structured data; or

(2) The measure specified in paragraph (d)(8)(ii)(A) of this section.

(C) Beginning 2014, only the measure specified in paragraph (d)(8)(ii)(B)(I) of this section.

(iii) *Exclusion in accordance with paragraph (a)(2) of this section*. (A) Any EP who either see no patients 2 years or

older, or who believes that all three vital signs of height, weight, and blood pressure of their patients have no relevance to their scope of practice.

(B) For 2013, either of the following:

(1) The exclusion specified in paragraph (d)(8)(iii)(A) of this section.

(2) The exclusion for an EP who—

(i) Sees no patients 3 years or older is excluded from recording blood pressure;

(ii) Believes that all three vital signs of height/length, weight, and blood pressure have no relevance to their scope of practice is excluded from recording them;

(iii) Believes that height/length and weight are relevant to their scope of practice, but blood pressure is not, is excluded from recording blood pressure; or

(iv) Believes that blood pressure is relevant to their scope of practice, but height/length and weight are not, is excluded from recording height/length and weight.

(C) Beginning 2014, only the exclusion specified in paragraph (d)(8)(iii)(B)(2) of this section.

(9)(i) *Objective.* Record smoking status for patients 13 years old or older.

(ii) *Measure.* Subject to paragraph (c) of this section, more than 50 percent of all unique patients 13 years old or older seen by the EP have smoking status recorded as structured data.

(iii) *Exclusion in accordance with paragraph (a)(2) of this section.* Any EP who sees no patients 13 years or older.

(10)(i) *Objective.* (A) Report ambulatory clinical quality measures to CMS or, in the case of Medicaid EPs, the States.

(B) Beginning 2013, this objective is reflected in the definition of a meaningful EHR user in § 495.4 and is no longer listed as an objective in this paragraph (d).

(ii) *Measure.* (A) Subject to paragraph (c) of this section, successfully report to CMS (or, in the case of Medicaid EPs, the States) ambulatory clinical quality measures selected by CMS in the manner specified by CMS (or in the case of Medicaid EPs, the States).

(B) Beginning 2013, this measure is reflected in the definition of a meaningful EHR user in § 495.4 and no longer

listed as a measure in this paragraph (d).

(11)(i) *Objective.* Implement one clinical decision support rules relevant to specialty or high clinical priority along with the ability to track compliance with that rule.

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

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

(B) Beginning 2014, provide patients the ability to view online, download, and transmit their health information within 4 business days of the information being available to the EP.

(ii) *Measure.* (A) Subject to paragraph (c) of this section, more than 50 percent of all patients who request an electronic copy of their health information are provided it within 3 business days.

(B) Beginning 2014, subject to paragraph (c) of this section, more than 50 percent of all unique patients seen by the EP during the EHR reporting period are provided timely (available to the patient within 4 business days after the information is available to the EP) online access to their health information subject to the EP's discretion to withhold certain information.

(iii) *Exclusion in accordance with paragraph (a)(2) of this section.* (A) Any EP that has no requests from patients or their agents for an electronic copy of patient health information during the EHR reporting period.

(B) Beginning 2014, any EP who neither orders nor creates any of the information listed for inclusion as part of this measure.

(13)(i) *Objective.* Provide clinical summaries for patients for each office visit.

(ii) *Measure.* Subject to paragraph (c) of this section, clinical summaries provided to patients for more than 50 percent of all office visits within 3 business days.

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

(14)(i) *Objective.* (A) Capability to exchange key clinical information (for example, problem list, medication list,

§ 495.6

42 CFR Ch. IV (10–1–15 Edition)

medication allergies, and diagnostic test results), among providers of care and patient authorized entities electronically.

(B) Beginning 2013, this objective is no longer required as part of the core set.

(ii) *Measure.* (A) Performed at least one test of certified EHR technology's capacity to electronically exchange key clinical information.

(B) Beginning 2013, this measure is no longer required as part of the core set.

(15)(i) *Objective.* Protect electronic health information created or maintained by the certified EHR technology through the implementation of appropriate technical capabilities.

(ii) *Measure.* Conduct or review a security risk analysis in accordance with the requirements under 45 CFR 164.308(a)(1) and implement security updates as necessary and correct identified security deficiencies as part of its risk management process.

(e) *Stage 1 menu set criteria for EPs.* An EP must meet five of the following objectives and associated measures, one of which must be either paragraph (e)(9) or (e)(10) of this section, except that the required number of objectives and associated measures is reduced by an EP's paragraph (a)(2) of this section exclusions specified in this paragraph. Beginning 2014, an EP must meet five of the following objectives and associated measures, one of which must be either paragraph (e)(9) or (10) of this section unless the EP has an exclusion from five or more objectives in this paragraph (e), in which case the EP must meet all remaining objectives and associated measures in paragraph (e) of this section.

(1)(i) *Objective.* Implement drug-formulary checks.

(ii) *Measure.* The EP has enabled this functionality and has access to at least one internal or external formulary for the entire EHR reporting period.

(iii) *Exclusion in accordance with paragraph (a)(2) of this section.* Any EP who writes fewer than 100 prescriptions during the EHR reporting period.

(2)(i) *Objective.* Incorporate clinical lab-test results into EHR as structured data.

(ii) *Measure.* Subject to paragraph (c) of this section, more than 40 percent of

all clinical lab tests results ordered by the EP during the EHR reporting period whose results are either in a positive/negative or numerical format are incorporated in certified EHR technology as structured data.

(iii) *Exclusion in accordance with paragraph (a)(2) of this section.* An EP who orders no lab tests whose results are either in a positive/negative or numeric format during the EHR reporting period.

(3)(i) *Objective.* Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, research, or outreach.

(ii) *Measure.* Subject to paragraph (c) of this section, generate at least one report listing patients of the EP with a specific condition.

(4)(i) *Objective.* Send reminders to patients per patient preference for preventive/follow-up care.

(ii) *Measure.* Subject to paragraph (c) of this section, more than 20 percent of all patients 65 years or older or 5 years old or younger were sent an appropriate reminder during the EHR reporting period.

(iii) *Exclusion in accordance with paragraph (a)(2) of this section.* An EP who has no patients 65 years old or older or 5 years old or younger with records maintained using certified EHR technology.

(5)(i) *Objective.* (A) Provide patients with timely electronic access to their health information (including lab results, problem list, medication lists, and allergies) within 4 business days of the information being available to the EP.

(B) Beginning 2014, this objective is no longer included in the menu set.

(ii) *Measure.* (A) At least 10 percent of all unique patients seen by the EP are provided timely (available to the patient within four business days of being updated in the certified EHR technology) electronic access to their health information subject to the EP's discretion to withhold certain information.

(B) Beginning 2014, this measure is no longer included in the menu set.

(iii) *Exclusion in accordance with paragraph (a)(2) of this section.* Any EP that neither orders nor creates any of the

information listed at 45 CFR 170.304(g) during the EHR reporting period.

(6)(i) *Objective.* Use certified EHR technology to identify patient-specific education resources and provide those resources to the patient if appropriate.

(ii) *Measure.* More than 10 percent of all unique patients seen by the EP are provided patient-specific education resources.

(7)(i) *Objective.* The EP who receives a patient from another setting of care or provider of care or believes an encounter is relevant should perform medication reconciliation.

(ii) *Measure.* Subject to paragraph (c) of this section, the EP performs medication reconciliation for more than 50 percent of transitions of care in which the patient is transitioned into the care of the EP.

(iii) *Exclusion in accordance with paragraph (a)(2) of this section.* An EP who was not the beneficiary of any transitions of care during the EHR reporting period.

(8)(i) *Objective.* The EP who transitions their patient to another setting of care or provider of care or refers their patient to another provider of care should provide summary care record for each transition of care or referral.

(ii) *Measure.* Subject to paragraph (c) of this section, the EP who transitions or refers their patient to another setting of care or provider of care provides a summary of care record for more than 50 percent of transitions of care and referrals.

(iii) *Exclusion in accordance with paragraph (a)(2) of this section.* An EP who neither transfers a patient to another setting nor refers a patient to another provider during the EHR reporting period.

(9)(i) *Objective.* (A) Capability to submit electronic data to immunization registries or immunization information systems and actual submission according to applicable law and practice.

(B) Beginning 2013, capability to submit electronic data to immunization registries or immunization information systems and actual submission except where prohibited and according to applicable law and practice.

(ii) *Measure.* Performed at least one test of certified EHR technology's ca-

capacity to submit electronic data to immunization registries and follow up submission if the test is successful (unless none of the immunization registries to which the EP submits such information has the capacity to receive the information electronically).

(iii) *Exclusion in accordance with paragraph (a)(2) of this section.* An EP who administers no immunizations during the EHR reporting period or where no immunization registry has the capacity to receive the information electronically.

(10)(i) *Objective.* (A) Capability to submit electronic syndromic surveillance data to public health agencies and actual submission according to applicable law and practice.

(B) Beginning 2013, capability to submit electronic syndromic surveillance data to public health agencies and actual submission except where prohibited and according to applicable law and practice.

(ii) *Measure.* Performed at least one test of certified EHR technology's capacity to provide electronic syndromic surveillance data to public health agencies and follow-up submission if the test is successful (unless none of the public health agencies to which an EP submits such information has the capacity to receive the information electronically).

(iii) *Exclusion in accordance with paragraph (a)(2) of this section.* An EP who does not collect any reportable syndromic information on their patients during the EHR reporting period or does not submit such information to any public health agency that has the capacity to receive the information electronically.

(f) *Stage 1 core criteria for eligible hospitals or CAHs.* An eligible hospital or CAH must meet the following objectives and associated measures except those objectives and associated measures for which an eligible hospital or CAH qualifies for a paragraph (b)(2) of this section exclusion specified in this paragraph:

(1)(i) *Objective.* Use CPOE for medication orders directly entered by any licensed healthcare professional who can enter orders into the medical record per State, local, and professional guidelines.

(ii) *Measure.* (A) Subject to paragraph (c) of this section, more than 30 percent of all unique patients with at least one medication in their medication list admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) have at least one medication order entered using CPOE.

(B) Subject to paragraph (c) of this section, more than 30 percent of medication orders created by the authorized providers of the eligible hospital or CAH for patients admitted to their inpatient or emergency departments (POS 21 or 23) during the EHR reporting period are recorded using computerized provider order entry, or the measure specified in paragraph (f)(1)(ii)(A) of this section.

(2)(i) *Objective.* Implement drug-drug and drug-allergy interaction checks.

(ii) *Measure.* The eligible hospital or CAH has enabled this functionality for the entire EHR reporting period.

(3)(i) *Objective.* Maintain an up-to-date problem list of current and active diagnoses.

(ii) *Measure.* More than 80 percent of all unique patients admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) have at least one entry or an indication that no problems are known for the patient recorded as structured data.

(4)(i) *Objective.* Maintain active medication list.

(ii) *Measure.* More than 80 percent of all unique patients admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) have at least one entry (or an indication that the patient is not currently prescribed any medication) recorded as structured data.

(5)(i) *Objective.* Maintain active medication allergy list.

(ii) *Measure.* More than 80 percent of all unique patients admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) have at least one entry (or an indication that the patient has no known medication allergies) recorded as structured data.

(6)(i) *Objective.* Record all of the following demographics;

- (A) Preferred language.
- (B) Gender.

(C) Race.

(D) Ethnicity.

(E) Date of birth.

(F) Date and preliminary cause of death in the event of mortality in the eligible hospital or CAH.

(ii) *Measure.* More than 50 percent of all unique patients admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) have demographics recorded as structured data.

(7)(i) *Objective.* Record and chart changes in the following vital signs:

(A) Height.

(B) Weight.

(C) Blood pressure.

(D) Calculate and display body mass index (BMI).

(E)(I) Plot and display growth charts for children 2–20 years, including BMI.

(2) For 2013, plot and display growth charts for patients 0–20 years, including body mass index, or paragraph (f)(7)(i)(E)(I) of this section.

(3) Beginning 2014, plot and display growth charts for patients 0–20 years, including body mass index.

(ii) *Measure.* (A) Subject to paragraph (c) of this section, for more than 50 percent of all unique patients age 2 and over admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23), height, weight, and blood pressure are recorded as structured data.

(B) For 2013—

(I) Subject to paragraph (c) of this section, more than 50 percent of all unique patients admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period have blood pressure (for patients age 3 and over only) and height/length and weight (for all ages) recorded as structured data; or

(2) The measure specified in paragraph (f)(7)(ii)(A) of this section.

(C) Beginning 2014, only the measure specified in paragraph (f)(7)(ii)(B)(I) of this section.

(8)(i) *Objective.* Record smoking for patients 13 years old or older.

(ii) *Measure.* Subject to paragraph (c) of this section, more than 50 percent of all unique patients 13 years old or older or admitted to the eligible hospital's inpatient or emergency department

(POS 21 or 23) have smoking status recorded as structured data.

(iii) *Exclusion in accordance with paragraph (b)(2) of this section.* Any eligible hospital or CAH that admits no patients 13 years or older to their inpatient or emergency department (POS 21 or 23).

(9)(i) *Objective.* (A) Report hospital clinical quality measures to CMS or, in the case of Medicaid eligible hospitals, the States.

(B) Beginning 2013, this objective is reflected in the definition of a meaningful EHR user in § 495.4 and no longer listed as an objective in this paragraph (f).

(ii) *Measure.* (A) Subject to paragraph (c) of this section, successfully report to CMS (or, in the case of Medicaid eligible hospitals or CAHs, the States) hospital clinical quality measures selected by CMS in the manner specified by CMS (or, in the case of Medicaid eligible hospitals or CAHs, the States).

(B) Beginning 2013, this measure is reflected in the definition of a meaningful EHR user in § 495.4 and no longer listed as a measure in this paragraph (f).

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

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

(11)(i) *Objective.* (A) Provide patients with an electronic copy of their health information (including diagnostic test results, problem list, medication lists, medication allergies, discharge summary, procedures), upon request.

(B) Beginning 2014, this objective is no longer required as part of the core set.

(ii) *Measure.* (A) Subject to paragraph (c) of this section, more than 50 percent of all patients of the inpatient or emergency departments of the eligible hospital or CAH (POS 21 or 23) who request an electronic copy of their health information are provided it within 3 business days.

(B) Beginning 2014, this measure is no longer required as part of the core set.

(iii) *Exclusion in accordance with paragraph (b)(2) of this section.* Any eligible hospital or CAH that has no requests

from patients or their agents for an electronic copy of patient health information during the EHR reporting period.

(12)(i) *Objective.* (A) Provide patients with an electronic copy of their discharge instructions at time of discharge, upon request.

(B) Beginning 2014, provide patients the ability to view online, download, and transmit information about a hospital admission.

(ii) *Measure.* (A) Subject to paragraph (c) of this section, more than 50 percent of all patients who are discharged from an eligible hospital or CAH's inpatient or emergency department (POS 21 or 23) and who request an electronic copy of their discharge instructions are provided it.

(B) Beginning 2014, subject to paragraph (c) of this section, more than 50 percent of all unique patients who are discharged from the inpatient or emergency department (POS 21 or 23) of an eligible hospital or CAH have their information available online within 36 hours of discharge.

(iii) *Exclusion in accordance with paragraph (b)(2) of this section.* (A) Any eligible hospital or CAH that has no requests from patients or their agents for an electronic copy of the discharge instructions during the EHR reporting period.

(B) Beginning 2014, this exclusion is no longer available.

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

(B) Beginning 2013, this objective is no longer required as part of the core set.

(ii) *Measure.* Performed at least one test of certified EHR technology's capacity to electronically exchange key clinical information.

(B) Beginning 2013, this measure is no longer required as part of the core set.

(14)(i) *Objective.* Protect electronic health information created or maintained by the certified EHR technology through the implementation of appropriate technical capabilities.

(ii) *Measure*. Conduct or review a security risk analysis in accordance with the requirements under 45 CFR 164.308(a)(1) and implement security updates as necessary and correct identified security deficiencies as part of its risk management process.

(g) *Stage 1 menu set criteria for eligible hospitals or CAHs*. Eligible hospitals or CAHs must meet five of the following objectives and associated measures, one which must be specified in paragraph (g)(8), (g)(9), or (g)(10) of this section, except that the required number of objectives and associated measures is reduced by a hospital's paragraph (b)(2) of this section exclusions specified in this paragraph. Beginning 2014, eligible hospitals or CAHs must meet five of the following objectives and associated measures, one which must be specified in paragraph (g)(8), (9), or (10) of this section:

(1)(i) *Objective*. Implement drug-formulary checks.

(ii) *Measure*. The eligible hospital or CAH has enabled this functionality and has access to at least one internal or external formulary for the entire EHR reporting period.

(2)(i) *Objective*. Record advance directives for patient 65 years old or older.

(ii) *Measure*. Subject to paragraph (c) of this section, more than 50 percent of all unique patients 65 years old or older admitted to the eligible hospital's or CAH's inpatient (POS 21) have an indication of an advance directive status recorded as structured data.

(iii) *Exclusion in accordance with paragraph (b)(2) of this section*. An eligible hospital or CAH that admits no patients age 65 years old or older during the EHR reporting period.

(3)(i) *Objective*. Incorporate clinical lab-test results into EHR as structured data.

(ii) *Measure*. Subject to paragraph (c) of this section, more than 40 percent of all clinical lab test results ordered by an authorized provider of the eligible hospital or CAH for patients admitted to its inpatient or emergency department (POS 21 and 23) during the EHR reporting period whose results are either in a positive/negative or numerical format are incorporated in certified EHR technology as structured data.

(4)(i) *Objective*. Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, research, or outreach.

(ii) *Measure*. Subject to paragraph (c) of this section, generate at least one report listing patients of the eligible hospital or CAH with a specific condition.

(5)(i) *Objective*. Use certified EHR technology to identify patient-specific education resources and provide those resources to the patient if appropriate.

(ii) *Measure*. More than 10 percent of all unique patients admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) are provided patient-specific education resources.

(6)(i) *Objective*. The eligible hospital or CAH who receives a patient from another setting of care or provider of care or believes an encounter is relevant should perform medication reconciliation.

(ii) *Measure*. Subject to paragraph (c) of this section, the eligible hospital or CAH performs medication reconciliation for more than 50 percent of transitions of care in which the patient is admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23).

(7)(i) *Objective*. The eligible hospital or CAH that transitions their patient to another setting of care or provider of care or refers their patient to another provider of care should provide summary care record for each transition of care or referral.

(ii) *Measure*. Subject to paragraph (c) of this section, the eligible hospital or CAH that transitions or refers their patient to another setting of care or provider of care provides a summary of care record for more than 50 percent of transitions of care and referrals.

(8)(i) *Objective*. (A) Capability to submit electronic data to immunization registries or immunization information systems and actual submission according to applicable law and practice.

(B) Beginning 2013, Capability to submit electronic data to immunization registries or immunization information systems and actual submission except where prohibited and according to applicable law and practice.

(ii) *Measure*. Performed at least one test of certified EHR technology's capacity to submit electronic data to immunization registries and follow up submission if the test is successful (unless none of the immunization registries to which the eligible hospital or CAH submits such information has the capacity to receive the information electronically).

(iii) *Exclusion in accordance with paragraph (b)(2) of this section*. An eligible hospital or CAH that administers no immunizations during the EHR reporting period or where no immunization registry has the capacity to receive the information electronically.

(9)(i) *Objective*. (A) Capability to submit electronic data on reportable (as required by State or local law) lab results to public health agencies and actual submission according to applicable law and practice.

(B) Beginning 2013, capability to submit electronic data on reportable (as required by State or local law) lab results to public health agencies and actual submission except where prohibited according to applicable law and practice.

(ii) *Measure*. Performed at least one test of certified EHR technology's capacity to provide electronic submission of reportable lab results to public health agencies and follow-up submission if the test is successful (unless none of the public health agencies to which an eligible hospital or CAH submits such information has the capacity to receive the information electronically).

(iii) *Exclusion in accordance with paragraph (b)(2) of this section*. No public health agency to which the eligible hospital or CAH submits such information has the capacity to receive the information electronically.

(10)(i) *Objective*. (A) Capability to submit electronic syndromic surveillance data to public health agencies and actual submission according to applicable law and practice.

(B) Beginning 2013, capability to submit electronic syndromic surveillance data to public health agencies and actual submission except where prohibited and according to applicable law and practice.

(ii) *Measure*. Performed at least one test of certified EHR technology's capacity to provide electronic syndromic surveillance data to public health agencies and follow-up submission if the test is successful (unless none of the public health agencies to which an eligible hospital or CAH submits information has the capacity to receive the information electronically).

(iii) *Exclusion in accordance with paragraph (a)(2) of this section*. No public health agency to which the eligible hospital or CAH submits information has the capacity to receive the information electronically.

(h) *Stage 2 criteria for EPs*—(1) *General rule regarding Stage 2 criteria for meaningful use for EPs*. Except as specified in paragraph (h)(2) of this section, EPs must meet all objectives and associated measures of the Stage 2 criteria specified in paragraph (j) of this section and 3 objectives of the EP's choice from paragraph (k) of this section to meet the definition of a meaningful EHR user.

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

(A) Must ensure that the objective in paragraph (j) or (k) of this section includes an option for the EP to attest that the objective is not applicable.

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

(C) Attests.

(ii)(A) An exclusion will reduce (by the number of exclusions applicable) the number of objectives that would otherwise apply in paragraph (j) of this section. For example, an EP that has an exclusion from one of the objectives in paragraph (j) of this section must meet 16 objectives from such paragraph to meet the definition of a meaningful EHR user.

(B) An exclusion does not reduce (by the number of exclusions applicable) the number of objectives that would otherwise apply in paragraph (k) of this section unless four or more exclusions apply. For example, an EP that has an exclusion for one of the objectives in paragraph (k) of this section

must meet three of the five non-excluded objectives from such paragraph to meet the definition of a meaningful EHR user. If an EP has an exclusion for four of the objectives in paragraph (k) of this section, then he or she must meet the remaining two non-excluded objectives from such paragraph to meet the definition of a meaningful EHR user.

(3) *Flexible options for using certified EHR technology in 2014.* For an EHR reporting period in 2014, if an EP is scheduled to begin Stage 2 in 2014, but is unable to fully implement all the functions of 2014 Edition certified EHR technology required for the objectives and associated measures of the Stage 2 criteria due to delays in availability, the EP may choose to satisfy the objectives and associated measures of the Stage 1 criteria that are applicable beginning 2014 using 2014 Edition certified EHR technology.

(i) *Stage 2 criteria for eligible hospitals and CAHs—(1) General rule regarding Stage 2 criteria for meaningful use for eligible hospitals or CAHs.* Except as specified in paragraph (i)(2) of this section, eligible hospitals and CAHs must meet all objectives and associated measures of the Stage 2 criteria specified in paragraph (1) of this section and three objectives of the eligible hospital's or CAH's choice from paragraph (m) of this section to meet the definition of a meaningful EHR user.

(2) *Exclusions for nonapplicable objectives.* (i) An eligible hospital or CAH may exclude a particular objective that includes an option for exclusion contained in paragraphs (l) or (m) of this section, if the hospital meets all of the following requirements:

(A) The hospital meets the criteria in the applicable objective that would permit an exclusion.

(B) The hospital so attests.

(ii)(A) An exclusion will reduce (by the number of exclusions applicable) the number of objectives that would otherwise apply in paragraph (1) of this section. For example, an eligible hospital that has an exclusion from 1 of the objectives in paragraph (1) of this section must meet 15 objectives from such paragraph to meet the definition of a meaningful EHR user.

(B) An exclusion does not reduce (by the number of exclusions applicable) the number of objectives that would otherwise apply in paragraph (m) of this section. For example, an eligible hospital that has an exclusion for one of the objectives in paragraph (m) of this section must meet three of the five nonexcluded objectives from such paragraph to meet the definition of a meaningful EHR user.

(3) *Flexible options for using certified EHR technology in 2014.* For an EHR reporting period in 2014, if an eligible hospital or CAH is scheduled to begin Stage 2 in 2014, but is unable to fully implement all the functions of 2014 Edition certified EHR technology required for the objectives and associated measures of the Stage 2 criteria due to delays in availability, the eligible hospital or CAH may choose to satisfy the objectives and associated measures of the Stage 1 criteria that are applicable beginning 2014 using 2014 Edition certified EHR technology.

(j) *Stage 2 core criteria for EPs.* An EP must satisfy the following objectives and associated measures, except those objectives and associated measures for which an EP qualifies for an exclusion under paragraph (h)(2) of this section specified in this paragraph (j).

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

(ii) *Measures.* Subject to paragraph (c) of this section—

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

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

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

(iii) *Exclusions in accordance with paragraph (h)(2) of this section.* (A) For

the measure specified in paragraph (j)(1)(ii)(A) of this section, any EP who writes fewer than 100 medication orders during the EHR reporting period.

(B) For the measure specified in paragraph (j)(1)(ii)(B) of this section, any EP who writes fewer than 100 laboratory orders during the EHR reporting period.

(C) For the measure specified in paragraph (j)(1)(ii)(C), any EP who writes fewer than 100 radiology orders during the EHR reporting period.

(2)(i) *Objective.* Generate and transmit permissible prescriptions electronically (eRx).

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

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

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

(3)(i) *Objective.* Record all of the following demographics:

(A) Preferred language.

(B) Sex.

(C) Race.

(D) Ethnicity.

(E) Date of birth.

(ii) *Measure.* More than 80 percent of all unique patients seen by the EP during the EHR reporting period have demographics recorded as structured data.

(4)(i) *Objective.* Record and chart changes in the following vital signs:

(A) Height/Length.

(B) Weight.

(C) Blood pressure (ages 3 and over).

(D) Calculate and display body mass index (BMI).

(E) Plot and display growth charts for patients 0–20 years, including body mass index.

(ii) *Measure.* Subject to paragraph (c) of this section, more than 80 percent of

all unique patients seen by the EP during the EHR reporting period have blood pressure (for patients age 3 and over only) and height/length and weight (for all ages) recorded as structured data.

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

(A) Sees no patients 3 years or older is excluded from recording blood pressure;

(B) Believes that all three vital signs of height/length, weight, and blood pressure have no relevance to their scope of practice is excluded from recording them;

(C) Believes that height/length and weight are relevant to their scope of practice, but blood pressure is not, is excluded from recording blood pressure; or

(D) Believes that blood pressure is relevant to their scope of practice, but height/length and weight are not, is excluded from recording height/length and weight.

(5)(i) *Objective.* Record smoking status for patients 13 years old or older.

(ii) *Measure.* Subject to paragraph (c) of this section, more than 80 percent of all unique patients 13 years old or older seen by the EP during the EHR reporting period have smoking status recorded as structured data.

(iii) *Exclusion in accordance with paragraph (h)(2) of this section.* Any EP who sees no patients 13 years old or older.

(6)(i) *Objective.* Use clinical decision support to improve performance on high priority health conditions.

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

(B) The EP has enabled and implemented the functionality for drug-drug and drug-allergy interaction checks for the entire EHR reporting period.

(iii) *Exclusion in accordance with paragraph (h)(2) of this section for paragraph (j)(6)(ii)(B) of this section.* An EP who

writes fewer than 100 medication orders during the EHR reporting period.

(7)(i) *Objective.* Incorporate clinical lab test results into Certified EHR Technology as structured data.

(ii) *Measure.* Subject to paragraph (c) of this section, more than 55 percent of all clinical lab tests results ordered by the EP during the EHR reporting period whose results are either in a positive/negative affirmation or numerical format are incorporated in Certified EHR Technology as structured data.

(iii) *Exclusion in accordance with paragraph (h)(2) of this section.* Any EP who orders no lab tests whose results are either in a positive/negative affirmation or numerical format during the EHR reporting period.

(8)(i) *Objective.* Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, research, or outreach.

(ii) *Measure.* Generate at least one report listing patients of the EP with a specific condition.

(9)(i) *Objective.* Use clinically relevant information to identify patients who should receive reminders for preventive/follow-up care and send these patients the reminder, per patient preference.

(ii) *Measure.* Subject to paragraph (c) of this section, more than 10 percent of all unique patients who have had two or more office visits with the EP within the 24 months before the beginning of the EHR reporting period were sent a reminder, per patient preference when available.

(iii) *Exclusion in accordance with paragraph (h)(2) of this section.* Any EP who has had no office visits in the 24 months before the beginning of the EHR reporting period.

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

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

(B) More than 5 percent of all unique patients seen by the EP during the EHR reporting period (or their authorized representatives) view, download or transmit to a third party their health information.

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

(A) Neither orders nor creates any of the information listed for inclusion as part of the measures in paragraphs (j)(10)(ii)(A) and (B) of this section, except for “Patient name” and “Provider's name and office contact information,” is excluded from both paragraphs (j)(10)(ii)(A) and (B) of this section; or

(B) Conducts 50 percent or more of his or her patient encounters in a county that does not have 50 percent or more of its housing units with 3Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period is excluded from paragraph (j)(10)(ii)(B) of this section.

(11)(i) *Objective.* Provide clinical summaries for patients for each office visit.

(ii) *Measure.* Subject to paragraph (c) of this section, clinical summaries provided to patients or patient-authorized representatives within 1 business day for more than 50 percent of office visits.

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

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

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

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

(13)(i) *Objective.* The EP who receives a patient from another setting of care

or provider of care or believes an encounter is relevant should perform medication reconciliation.

(ii) *Measure.* Subject to paragraph (c) of this section, the EP performs medication reconciliation for more than 50 percent of transitions of care in which the patient is transitioned into the care of the EP.

(iii) *Exclusion in accordance with paragraph (h)(2) of this section.* Any EP who was not the beneficiary of any transitions of care during the EHR reporting period.

(14)(i) *Objective.* The EP who transitions their patient to another setting of care or provider of care or refers their patient to another provider of care provides a summary care record for each transition of care or referral.

(ii) *Measures.* (A) Subject to paragraph (c) of this section, the EP that transitions or refers their patient to another setting of care or provider of care provides a summary of care record for more than 50 percent of transitions of care and referrals;

(B) Subject to paragraph (c) of this section, the EP that transitions or refers their patient to another setting of care or provider of care provides a summary of care record for more than 10 percent of such transitions and referrals either—

(1) Electronically transmitted using Certified EHR Technology to a beneficiary; or

(2) Where the beneficiary receives the summary of care record via exchange facilitated by an organization that is a NwHIN Exchange participant or in a manner that is consistent with the governance mechanism ONC establishes for the nationwide health information network, and

(C) Subject to paragraph (c) of this section an EP must satisfy one of the following:

(1) Conducts one or more successful electronic exchanges of a summary of care record meeting the measure specified in paragraph (j)(14)(ii)(B) of this section with a beneficiary using technology to receive the summary of care record that was designed by a different EHR developer than the sender's EHR technology certified at 45 CFR 170.314(b)(2); or

(2) Conducts one or more successful tests with the CMS designated test EHR during the EHR reporting period.

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

(15)(i) *Objective.* Capability to submit electronic data to immunization registries or immunization information systems except where prohibited, and in accordance with applicable law and practice.

(ii) *Measure.* Successful ongoing submission of electronic immunization data from Certified EHR Technology to an immunization registry or immunization information system for the entire EHR reporting period.

(iii) *Exclusion in accordance with paragraph (h)(2) of this section.* Any EP that meets one or more of the following criteria:

(A) Does not administer any of the immunizations to any of the populations for which data is collected by their jurisdiction's immunization registry or immunization information system during the EHR reporting period.

(B) Operates in a jurisdiction for which no immunization registry or immunization information system is capable of accepting the specific standards required for Certified EHR Technology at the start of his or her EHR reporting period.

(C) Operates in a jurisdiction where no immunization registry or immunization information system provides information timely on capability to receive immunization data.

(D) Operates in a jurisdiction for which no immunization registry or immunization information system that is capable of accepting the specific standards required by Certified EHR Technology at the start of his or her EHR reporting period can enroll additional EPs.

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

(ii) *Measure.* Conduct or review a security risk analysis in accordance with the requirements under 45 CFR

§ 495.6

42 CFR Ch. IV (10–1–15 Edition)

164.308(a)(1), including addressing the encryption/security of data stored in Certified EHR Technology in accordance with requirements under 45 CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3), and implement security updates as necessary and correct identified security deficiencies as part of the EP's risk management process.

(17)(i) *Objective.* Use secure electronic messaging to communicate with patients on relevant health information.

(ii) *Measure.* A secure message was sent using the electronic messaging function of Certified EHR Technology by more than 5 percent of unique patients (or their authorized representatives) seen by the EP during the EHR reporting period.

(iii) *Exclusion in accordance with paragraph (h)(2) of this section.* Any EP who meets one or more of the following criteria:

(A) Has no office visits during the EHR reporting period.

(B) Who conducts 50 percent or more of his or her patient encounters in a county that does not have 50 percent or more of its housing units with 3Mbps broadband availability according to the latest information available from the FCC on the first day of their EHR reporting period.

(k) *Stage 2 menu set criteria for EPs.* An EP must meet 3 of the following objectives and associated measures, unless the EP has an exclusion from 4 or more objectives in this paragraph (k) of this section, in which case the EP must meet all remaining objectives and associated measures.

(1)(i) *Objective.* Imaging results consisting of the image itself and any explanation or other accompanying information are accessible through Certified EHR Technology.

(ii) *Measure.* Subject to paragraph (c) of this section, more than 10 percent of all tests whose result is one or more images ordered by the EP during the EHR reporting period are accessible through Certified EHR Technology.

(iii) *Exclusion in accordance with paragraph (h)(2) of this section.* Any EP who meets one or more of the following criteria.

(A) Orders less than 100 tests whose result is an image during the EHR reporting period.

(B) Has no access to electronic imaging results at the start of the EHR reporting period.

(2)(i) *Objective.* Record patient family health history as structured data.

(ii) *Measure.* More than 20 percent of all unique patients seen by the EP during the EHR reporting period have a structured data entry for one or more first-degree relatives.

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

(3)(i) *Objective.* Capability to submit electronic syndromic surveillance data to public health agencies, except where prohibited, and in accordance with applicable law and practice.

(ii) *Measure.* Successful ongoing submission of electronic syndromic surveillance data from Certified EHR Technology to a public health agency for the entire EHR reporting period.

(iii) *Exclusion in accordance with paragraph (h)(2) of this section.* Any EP that meets one or more of the following criteria:

(A) Is not in a category of providers who collect ambulatory syndromic surveillance information on their patients during the EHR reporting period.

(B) Operates in a jurisdiction for which no public health agency is capable of receiving electronic syndromic surveillance data in the specific standards required for Certified EHR Technology at the start of their EHR reporting period.

(C) Operates in a jurisdiction where no public health agency provides information timely on capability to receive syndromic surveillance data.

(D) Operates in a jurisdiction for which no public health agency that is capable of accepting the specific standards required by Certified EHR Technology at the start of their EHR reporting period can enroll additional EPs.

(4)(i) *Objective.* Capability to identify and report cancer cases to a public health central cancer registry, except where prohibited, and in accordance with applicable law and practice.

(ii) *Measure.* Successful ongoing submission of cancer case information from Certified EHR Technology to a

public health central cancer registry for the entire EHR reporting period.

(iii) *Exclusion in accordance with paragraph (h)(2) of this section.* Any EP who meets one or more of the following—

(A) Does not diagnose or directly treat cancer.

(B) Operates in a jurisdiction for which no public health agency is capable of receiving electronic cancer case information in the specific standards required for Certified EHR Technology at the start of their EHR reporting period.

(C) Operates in a jurisdiction where no public health agency provides information timely on capability to receive electronic cancer case information.

(D) Operates in a jurisdiction for which no public health agency that is capable of receiving electronic cancer case information in the specific standards required for Certified EHR Technology at the beginning of their EHR reporting period can enroll additional EPs.

(5)(i) *Objective.* Capability to identify and report specific cases to a specialized registry (other than a cancer registry), except where prohibited, and in accordance with applicable law and practice.

(ii) *Measure.* Successful ongoing submission of specific case information from Certified EHR Technology to a specialized registry for the entire EHR reporting period.

(iii) *Exclusion in accordance with paragraph (h)(2) of this section.* Any EP who meets one or more of the following criteria:

(A) Does not diagnose or directly treat any disease associated with a specialized registry sponsored by a national specialty society for which the EP is eligible, or the public health agencies in their jurisdiction;

(B) Operates in a jurisdiction for which no specialized registry sponsored by a public health agency or by a national specialty society for which the EP is eligible is capable of receiving electronic specific case information in the specific standards required by Certified EHR Technology at the beginning of their EHR reporting period;

(C) Operates in a jurisdiction where no public health agency or national specialty society for which the EP is

eligible provides information timely on capability to receive information into their specialized registries; or

(D) Operates in a jurisdiction for which no specialized registry sponsored by a public health agency or by a national specialty society for which the EP is eligible that is capable of receiving electronic specific case information in the specific standards required by Certified EHR Technology at the beginning of his or her EHR reporting period can enroll additional EPs.

(6)(i) *Objective.* Record electronic notes in patient records.

(ii) *Measure.* Enter at least one electronic progress note created, edited, and signed by an EP for more than 30 percent of unique patients with at least one office visit during the EHR reporting period. The text of the electronic note must be text-searchable and may contain drawings and other content.

(1) *Stage 2 core criteria for eligible hospitals or CAHs.* An eligible hospital or CAH must meet the following objectives and associated measures except those objectives and associated measures for which an eligible hospital or CAH qualifies for an exclusion under paragraph (i)(2) of this section.

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

(ii) *Measures.* Subject to paragraph (c) of this section, more than—

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

(B) Thirty percent of laboratory orders created by authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using computerized provider order entry, and

(C) Thirty percent of radiology orders created by authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are

§ 495.6

42 CFR Ch. IV (10–1–15 Edition)

recorded using computerized provider order entry.

(2)(i) *Objective.* Record all of the following demographics:

- (A) Preferred language.
- (B) Sex.
- (C) Race.
- (D) Ethnicity.
- (E) Date of birth.

(F) Date and preliminary cause of death in the event of mortality in the eligible hospital or CAH.

(ii) *Measure.* More than 80 percent of all unique patients admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period have demographics recorded as structured data.

(3)(i) *Objective.* Record and chart changes in the following vital signs:

- (A) Height/Length.
- (B) Weight.
- (C) Blood pressure (ages 3 and over).
- (D) Calculate and display body mass index (BMI).
- (E) Plot and display growth charts for patients 0–20 years, including body mass index.

(ii) *Measure.* Subject to paragraph (c) of this section, more than 80 percent of all unique patients admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period have blood pressure (for patients age 3 and over only) and height/length and weight (for all ages) recorded as structured data.

(4)(i) *Objective.* Record smoking status for patients 13 years old or older.

(ii) *Measure.* Subject to paragraph (c) of this section, more than 80 percent of all unique patients 13 years old or older admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period have smoking status recorded as structured data.

(iii) *Exclusion in accordance with paragraph (i)(2) of this section.* Any eligible hospital or CAH that admits no patients 13 years old or older to their inpatient or emergency department (POS 21 or 23) during the EHR reporting period.

(5)(i) *Objective.* Use clinical decision support to improve performance on high priority health conditions.

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

(B) The eligible hospital or CAH has enabled and implemented the functionality for drug-drug and drug-allergy interaction checks for the entire EHR reporting period.

(6)(i) *Objective.* Incorporate clinical lab test results into Certified EHR Technology as structured data.

(ii) *Measure.* Subject to paragraph (c) of this section, more than 55 percent of all clinical lab tests results ordered by authorized providers of the eligible hospital or CAH for patients admitted to its inpatient or emergency department (POS 21 or 23) during the EHR reporting period whose results are either in a positive/negative affirmation or numerical format are incorporated in Certified EHR Technology as structured data.

(7)(i) *Objective.* Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, research or outreach.

(ii) *Measure.* Generate at least one report listing patients of the eligible hospital or CAH with a specific condition.

(8)(i) *Objective.* Provide patients the ability to view online, download, and transmit information about a hospital admission.

(ii) *Measures.* (A) More than 50 percent of all unique patients who are discharged from the inpatient or emergency department (POS 21 or 23) of an eligible hospital or CAH have their information available online within 36 hours of discharge; and

(B) More than 5 percent of all unique patients who are discharged from the inpatient or emergency department (POS 21 or 23) of an eligible hospital or CAH (or their authorized representative) view, download or transmit to a third party their information during the EHR reporting period.

(iii) *Exclusion in accordance with paragraph (i)(2) of this section.* Any eligible

hospital or CAH that is located in a county that does not have 50 percent or more of its housing units with 3Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period is excluded from paragraph (1)(8)(ii)(B) of this section.

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

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

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

(ii) *Measure.* Subject to paragraph (c) of this section, the eligible hospital or CAH performs medication reconciliation for more than 50 percent of transitions of care in which the patient is admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23).

(11)(i) *Objective.* The eligible hospital or CAH that transitions their patient to another setting of care or provider of care or refers their patient to another provider of care provides a summary care record for each transition of care or referral.

(ii) *Measures.* (A) Subject to paragraph (c) in this section, the eligible hospital or CAH that transitions or refers their patient to another setting of care or provider of care provides a summary of care record for more than 50 percent of transitions of care and referrals.

(B) Subject to paragraph (c) in this section, the eligible hospital or CAH that transitions their patient to another setting of care or provider of care provides a summary of care record for more than 10 percent of such transitions and referrals either—

(1) Electronically transmitted using Certified EHR Technology to a beneficiary; or

(2) Where the beneficiary receives the summary of care record via exchange facilitated by an organization that is a NwHIN Exchange participant or in a manner that is consistent with the governance mechanism ONC establishes for the nationwide health information network; and

(C) Subject to paragraph (c) of this section an eligible hospital or CAH must satisfy one of the following:

(1) Conducts one or more successful electronic exchanges of a summary of care record meeting the measure specified in paragraph (1)(11)(ii)(B) of this section with a beneficiary using technology to receive the summary of care record that was designed by a different EHR developer than the sender's EHR technology certified at 45 CFR 107.314(b)(2); or

(2) Conducts one or more successful tests with the CMS designated test EHR during the EHR reporting period.

(12)(i) *Objective.* Capability to submit electronic data to immunization registries or immunization information systems except where prohibited, and in accordance with applicable law and practice.

(ii) *Measure.* Successful ongoing submission of electronic immunization data from Certified EHR Technology to an immunization registry or immunization information system for the entire EHR reporting period.

(iii) *Exclusion in accordance with paragraph (i)(2) of this section.* Any eligible hospital or CAH that meets one or more of the following criteria:

(A) The eligible hospital or CAH does not administer any of the immunizations to any of the populations for which data is collected by their jurisdiction's immunization registry or immunization information system during the EHR reporting period.

(B) The eligible hospital or CAH operates in a jurisdiction for which no immunization registry or immunization information system is capable of accepting the specific standards required for Certified EHR Technology at the start of their EHR reporting period.

(C) The eligible hospital or CAH operates in a jurisdiction where no immunization registry or immunization information system provides information

timely on capability to receive immunization data.

(D) Operates in a jurisdiction for which no immunization registry or immunization information system that is capable of accepting the specific standards required by Certified EHR Technology at the start of their EHR reporting period can enroll additional eligible hospitals or CAHs.

(13)(i) *Objective.* Capability to submit electronic reportable laboratory results to public health agencies, where except where prohibited, and in accordance with applicable law and practice.

(ii) *Measure.* Successful ongoing submission of electronic reportable laboratory results from Certified EHR Technology to a public health agency for the entire EHR reporting period.

(iii) *Exclusion in accordance with paragraph (i)(2) of this section.* Any eligible hospital or CAH that meets one or more of the following criteria:

(A) Operates in a jurisdiction for which no public health agency is capable of receiving electronic reportable laboratory results in the specific standards required for Certified EHR Technology at the start of their EHR reporting period.

(B) Operates in a jurisdiction for which no public health agency provides information timely on capability to receive electronic reportable laboratory results.

(C) Operates in a jurisdiction for which no public health agency that is capable of accepting the specific standards required by Certified EHR Technology at the start of their EHR reporting period can enroll additional eligible hospitals or CAHs.

(14)(i) *Objective.* Capability to submit electronic syndromic surveillance data to public health agencies, except where prohibited, and in accordance with applicable law and practice.

(ii) *Measure.* Successful ongoing submission of electronic syndromic surveillance data from Certified EHR Technology to a public health agency for the entire EHR reporting period.

(iii) *Exclusion in accordance with paragraph (i)(2) of this section.* Any eligible hospital or CAH that meets one or more of the following criteria:

(A) Does not have an emergency or urgent care department.

(B) Operates in a jurisdiction for which no public health agency is capable of receiving electronic syndromic surveillance data in the specific standards required for Certified EHR Technology at the start of their EHR reporting period or can enroll additional eligible hospitals or CAHs.

(C) Operates in a jurisdiction for which no public health agency provides information timely on capability to receive syndromic surveillance data.

(D) Operates in a jurisdiction for which no public health agency that is capable of accepting the specific standards required by Certified EHR Technology at the start of their EHR reporting period can enroll additional eligible hospitals or CAHs.

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

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

(16)(i) *Objective.* Automatically track medications from order to administration using assistive technologies in conjunction with an electronic medication administration record (eMAR).

(ii) *Measure.* Subject to paragraph (c) of this section, more than 10 percent of medication orders created by authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period for which all doses are tracked using eMAR.

(iii) *Exclusion in accordance with paragraph (i)(2) of this section.* Any eligible hospital or CAH with an average daily inpatient census of fewer than 10 patients.

(m) *Stage 2 menu set criteria for eligible hospitals or CAHs.* An eligible hospital or CAH must meet the measure criteria

for three of the following objectives and associated measures.

(1)(i) *Objective.* Record whether a patient 65 years old or older has an advance directive.

(ii) *Measure.* Subject to paragraph (c) of this section, more than 50 percent of all unique patients 65 years old or older admitted to the eligible hospital's or CAH's inpatient department (POS 21) during the EHR reporting period have an indication of an advance directive status recorded as structured data.

(iii) *Exclusion in accordance with paragraph (i)(2) of this section.* Any eligible hospital or CAH that admits no patients age 65 years old or older during the EHR reporting period.

(2)(i) *Objective.* Imaging results consisting of the image itself and any explanation or other accompanying information are accessible through Certified EHR Technology.

(ii) *Measure.* Subject to paragraph (c) of this section, more than 10 percent of all tests whose result is an image ordered by an authorized provider of the eligible hospital or CAH for patients admitted to its inpatient or emergency department (POS 21 or 23) during the EHR reporting period are accessible through Certified EHR Technology.

(3)(i) *Objective.* Record patient family health history as structured data.

(ii) *Measure.* More than 20 percent of all unique patients admitted to the eligible hospital or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period have a structured data entry for one or more first-degree relatives.

(4)(i) *Objective.* Generate and transmit permissible discharge prescriptions electronically (eRx).

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

(iii) *Exclusion in accordance with paragraph (i)(2) of this section.* Any eligible hospital or CAH that does not have an internal pharmacy that can accept electronic prescriptions and there are no pharmacies that accept electronic

prescriptions within 10 miles at the start of its EHR reporting period.

(5)(i) *Objective.* Record electronic notes in patient records.

(ii) *Measure.* Enter at least one electronic progress note created, edited and signed by an authorized provider of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) for more than 30 percent of unique patients admitted to the eligible hospital or CAH's inpatient or emergency department during the EHR reporting period. The text of the electronic note must be text-searchable and may contain drawings and other content.

(6)(i) *Objective.* Provide structured electronic lab results to ambulatory providers.

(ii) *Measures.* Hospital labs send structured electronic clinical lab results to the ordering provider for more than 20 percent of—

(A) The electronic lab orders received; or

(B) The lab orders received.

[75 FR 44565, July 28, 2010, as amended at 75 FR 81887, Dec. 29, 2010; 77 FR 54149, Sept. 4, 2012; 77 FR 64758, Oct. 23, 2012; 77 FR 72991, Dec. 7, 2012; 79 FR 52932, Sept. 4, 2014]

§ 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) *Attestation.* 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—

(A) Used certified EHR technology, and specify the technology used;

(B) Satisfied the required objectives and associated measures under § 495.6(d) and § 495.6(e) of this subpart;

(C) 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;

(ii) *Additional requirements for Medicaid EPs.* For Medicaid EPs, if, in accordance with § 495.316 and § 495.332,

§ 495.8

42 CFR Ch. IV (10–1–15 Edition)

CMS has approved a State's revised definition for meaningful use, in addition to meeting paragraphs (a)(1)(i) through (ii) of this section, the EP must also demonstrate meeting the State revised definition using the method approved by CMS; and

(iii) *Exception for Medicaid EPs.* If a Medicaid EP has adopted, implemented or upgraded certified EHR technology in the first payment year, the EP need not demonstrate meaningful use until the second payment year, as described in § 495.6 and § 495.8 of this subpart.

(2) For CY 2012 and subsequent years—

(i) *Attestation.* 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—

(A) Used certified EHR technology and specify the technology used.

(B) Satisfied the required objectives and associated measures under § 495.6 for the EP's stage of meaningful use.

(C) 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.

(D) For 2014 only, if the EP uses one of the options specified under § 495.6(a)(4) or (h)(3), the EP must attest that he or she is unable to fully implement 2014 Edition certified EHR technology for an EHR reporting period in 2014 due to delays in 2014 Edition certified EHR technology availability.

(ii) *Reporting clinical quality information.* Successfully report the clinical quality measures selected by CMS to CMS or the States, as applicable, in the form and manner specified by CMS or the States, as applicable.

(iii) *Additional requirements for Medicaid EPs.* For Medicaid EPs, if, in accordance with § 495.316 and § 495.332, CMS has approved a State's additional criteria for meaningful use, in addition to meeting paragraphs (a)(2)(i) through (iii), the EP must also demonstrate meeting such additional criteria using the method approved by CMS.

(iv) *Exception for Medicaid EPs.* If a Medicaid EP has adopted, implemented, or upgrade certified EHR tech-

nology in the first payment year, the EP need not demonstrate that it is a meaningful EHR user until the second payment year, as described in § 495.6 and § 495.8 of this subpart.

(v) *Exception for Medicare EPs for 2012 and 2013—Participation in the Physician Quality Reporting System-Medicare EHR Incentive Pilot.* To satisfy the clinical quality measure reporting requirements of meaningful use, aside from attestation, an EP participating in the Physician Quality Reporting System may also participate in the Physician Quality Reporting System-Medicare EHR Incentive Pilot through one of the following methods:

(A) Submission of data extracted from the EP's certified EHR technology through a Physician Quality Reporting System qualified EHR data submission vendor; or

(B) Submission of data extracted from the EP's certified EHR technology, which must also be through a Physician Quality Reporting System qualified EHR.

(3) For all CYs, an EP who practices in multiple physical locations, not all of which have certified EHR technology available, will demonstrate meaningful use using only the locations where the EP has certified EHR technology available. (See also § 495.4 regarding the definition of meaningful EHR user).

(b) *Demonstration by eligible hospitals and CAHs.* To successfully demonstrate that it is a meaningful EHR user, an eligible hospital or CAH must the following requirements:

(1) For FY 2011—

(i) *Attestation.* 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—

(A) Used certified EHR and specify the technology used.

(B) Satisfied the required objectives and associated measures under § 495.6(f) and § 495.6(g).

(C) Must specify the EHR reporting period and provide the result of each applicable measure for all patients admitted to the inpatient or emergency department (POS 21 or 23) of the hospital during the EHR reporting period

for which a selected measure is applicable.

(ii) *Additional requirements for Medicaid eligible hospitals.* For Medicaid eligible hospitals, if, in accordance with § 495.316 and § 495.332, CMS has approved a State's revised definition for meaningful use, in addition to meeting paragraphs (b)(1)(i) through (ii) of this section, the eligible hospital must also demonstrate meeting the State's revised definition using the method approved by CMS.

(iv) *Exception for Medicaid eligible hospitals.* If a Medicaid eligible hospital has adopted, implemented or upgraded certified EHR technology in the first payment year, the eligible hospital need not demonstrate meaningful use until the second payment year, as described in § 495.6 and § 495.8 of this subpart.

(2) For FY 2012 and subsequent years—

(i) *Attestation.* 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—

(A) Used certified EHR and specify the technology used;

(B) Satisfied the required objectives and associated measures under § 495.6 for the eligible hospital or CAH's stage of meaningful use.

(C) Must specify the EHR reporting period and provide the result of each applicable measure for all patients admitted to the inpatient or emergency department (POS 21 or 23) of the hospital during the EHR reporting period for which a selected measure is applicable.

(D) For 2014 only, if the eligible hospital or CAH uses one of the options specified under § 495.6(b)(4) or (1)(3), it must attest that it is unable to fully implement 2014 Edition certified EHR technology for an EHR reporting period in 2014 due to delays in 2014 Edition certified EHR technology availability.

(ii) *Reporting clinical quality information.* Successfully report the clinical quality measures selected by CMS to CMS or the States, as applicable, in the form and manner specified by CMS or the States, as applicable.

(iv) *Additional requirements for Medicaid eligible hospitals.* For Medicaid eligible hospitals if, in accordance with § 495.316 and § 495.332, CMS has approved a State's revised definition for meaningful use, in addition to meeting paragraphs (b)(2)(i) through (iii) of this section, the eligible hospital must also demonstrate meeting the State's revised definition using the method approved by CMS.

(v) *Exception for Medicare EPs for 2012 and 2013—Participation in the Physician Quality Reporting System-Medicare EHR Incentive Pilot.* To satisfy the clinical quality measure reporting requirements of meaningful use, aside from attestation, an EP participating in the Physician Quality Reporting System may also participate in the Physician Quality Reporting System-Medicare EHR Incentive Pilot through one of the following methods:

(A) Submission of data extracted from the EP's certified EHR technology through a Physician Quality Reporting System qualified EHR data submission vendor; or

(B) Submission of data extracted from the EP's certified EHR technology, which must also be through a Physician Quality Reporting System qualified EHR.

(vi) *Exception for Medicare eligible hospitals and CAHs for FY 2012 and 2013—Participation in the Medicare EHR Incentive Program Electronic Reporting Pilot.* In order to satisfy the clinical quality measure reporting requirements of meaningful use, aside from attestation, a Medicare eligible hospital or CAH may participate in the Medicare EHR Incentive Program Electronic Reporting Pilot.

(c) *Review of meaningful use.* (1) CMS (and in the case of Medicaid EPs and eligible hospitals, States) may review an EP, eligible hospital or CAH's demonstration of meaningful use.

(2) All EPs, eligible hospitals, and CAHs must keep documentation supporting their demonstration of meaningful use for 6 years.

[75 FR 44565, July 28, 2010, as amended at 76 FR 73473, Nov. 28, 2011; 76 FR 74584, Nov. 30, 2011; 77 FR 54157, Sept. 4, 2012; 77 FR 68565, Nov. 15, 2012; 77 FR 69372, Nov. 16, 2012; 79 FR 52933, Sept. 4, 2014]

§ 495.10

§ 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, business email address, and phone number.

(4) Such other information as specified by CMS.

(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) which may be the EP's Social Security Number (SSN) 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, eligible hospital or CAH 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) After receiving at least one EHR incentive payment, may switch between the two EHR incentive programs only one time, and only for a payment year before 2015;

(3) Must, for each payment year, meet all of the applicable requirements, including applicable patient volume requirements, for the program in which he or she chooses to participate (Medicare or Medicaid);

42 CFR Ch. IV (10–1–15 Edition)

(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; and

(5) Is placed in the payment year the EP would have been in had the EP begun in and remained in the program to which he or she has switched. 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 re-assignments.* (1) EPs are permitted to reassign their incentive payments to their employer or to an entity with which they have a contractual arrangement allowing the employer or entity to bill and receive payment for the EP's covered professional services.

(2)(i) Assignments in Medicare must be consistent with Section 1842(b)(6)(A) of the Act and 42 CFR part 424 subpart F.

(ii) Medicaid EPs may also assign their incentive payments to a TIN for an entity promoting the adoption of EHR technology, consistent with subpart D of this part.

(3) Each EP may reassign the entire amount of the incentive payment to only one employer or entity.

[75 FR 44565, July 28, 2010, as amended at 77 FR 54157, Sept. 4, 2012]

Subpart B—Requirements Specific to the Medicare Program

§ 495.100 Definitions.

In this subpart unless otherwise indicated—

Covered professional services means (as specified in section 1848(k)(3) of the Act) services furnished by an EP for which payment is made under, or is based on, the Medicare physician fee schedule.

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, and excluding those hospital units specified in § 412.25 of this chapter.

Eligible professional (EP) means a physician as defined in section 1861(r) of

the Act, which includes, with certain limitations, 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 a geographic 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 applicable to a payment year or payment adjustment year in which a cost reporting period begins.

Qualifying eligible professional (qualifying EP) means an EP who is a meaningful EHR user for the EHR reporting period applicable to a payment or payment adjustment year and who is not a hospital-based EP, as determined for that payment or payment adjustment year.

Qualifying hospital means an eligible hospital that is a meaningful EHR user for the EHR reporting period applicable to a payment or payment adjustment year.

[75 FR 44565, July 28, 2010, as amended at 77 FR 54157, Sept. 4, 2012]

§ 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 must be paid to a qualifying EP (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 to 75 percent of the estimated allowed charges for covered professional services furnished by the EP during the payment year.

(2) For purposes of this paragraph (a) of this section, 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 paragraphs (b)(2) and (c) of this section, the amount of the incentive payment under paragraph (a) of this section 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 EP 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 EP is 2014, then the payment limit for a payment year for the qualifying EP is the same as the amount specified in paragraph (b)(1) of this section 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 payment limit specified in this paragraph for such EP for such year and any subsequent year is \$0.

(c) *Increase in incentive payment limit for EPs who predominantly furnish services in a geographic HPSA.* In the case of a qualifying EP who furnishes more than 50 percent of his or her covered professional services during the payment year in a geographic HPSA that is designated as of December 31 of the prior year, the incentive payment limit determined under paragraph (b) of this section is to be increased by 10 percent.

(d) *Payment adjustment effective in CY 2015 and subsequent years for nonqualifying EPs.* (1)(i) Subject to paragraphs (d)(3) and (4) of this section, beginning 2015, for covered professional services furnished by an EP who is not hospital-based, and who is not a qualifying EP by virtue of not being a meaningful EHR user (for the EHR reporting period applicable to the payment adjustment year), the payment amount for

such services is equal to the product of the applicable percent specified in paragraph (d)(2) of this section and the Medicare physician fee schedule amount for such services.

(2) *Applicable percent.* Applicable percent is as follows:

(i) For 2015, 99 percent if the EP is not subject to the payment adjustment for an EP who is not a successful electronic prescriber under section 1848(a)(5) of the Act, or 98 percent if the EP is subject to the payment adjustment for an EP who is not a successful electronic prescriber under section 1848(a)(5) of the Act).

(ii) For 2016, 98 percent.

(iii) For 2017, 97 percent.

(iv) For 2018 and subsequent years, 97 percent, except as provided in paragraph (d)(3) of this section.

(3) *Decrease in applicable percent in certain circumstances.* If, beginning CY 2018 and for each subsequent year, the Secretary finds that the proportion of EPs who are meaningful EHR users is less than 75 percent, the applicable percent must be decreased by 1 percentage point for EPs from the applicable percent in the preceding year, but in no case will the applicable percent be less than 95 percent.

(4) *Exceptions.* The Secretary may, on a case-by-case basis, exempt an EP from the application of the payment adjustment under paragraph (d)(1) of this section if the Secretary determines that compliance with the requirement for being a meaningful EHR user would result in a significant hardship for the EP. To be considered for an exception, an EP must submit, in the manner specified by CMS, an application demonstrating that it meets one or more of the criteria in this paragraph (d)(4) unless otherwise specified in the criteria. The Secretary's determination to grant an EP an exemption may be renewed on an annual basis, provided that in no case may an EP be granted an exemption for more than 5 years.

(i) During any 90-day period from the beginning of the year that is 2 years before the payment adjustment year to July 1 of the year preceding the payment adjustment year, or a later date specified by CMS, the EP was located in an area without sufficient Internet

access to comply with the meaningful use objectives requiring internet connectivity, and faced insurmountable barriers to obtaining such internet connectivity. Applications requesting this exception must be submitted no later than July 1 of the year before the applicable payment adjustment year, or a later date specified by CMS.

(ii) The EP has been practicing for less than 2 years.

(iii)(A) During the calendar year that is 2 calendar years before the payment adjustment year, the EP that has previously demonstrated meaningful use faces extreme and uncontrollable circumstances that prevent it from becoming a meaningful EHR user. Applications requesting this exception must be submitted no later than July 1 of the year before the applicable payment adjustment year, or a later date specified by CMS.

(B) During the calendar year preceding the payment adjustment year, the EP that has not previously demonstrated meaningful use faces extreme and uncontrollable circumstances that prevent it from becoming a meaningful EHR user. Applications requesting this exception must be submitted by July 1 of the year before the applicable payment adjustment year, or a later date specified by CMS.

(iv) An EP may request an exception through an application submitted by July 1 of the year before the applicable payment adjustment year, or a later date specified by CMS due to difficulty in meeting meaningful use based on any one of the following during the period that begins 2 calendar years before the payment adjustment year through the application deadline:

(A) The EP practices at multiple locations and can demonstrate inability to control the availability of Certified EHR Technology at one such practice location or a combination of practice locations, and where the location or locations constitute more than 50 percent of their patient encounters.

(B) The EP can demonstrate difficulty in meeting meaningful use on the basis of lack of face-to-face or telemedicine interaction with patients and lack of need for follow up with patients.

(C) The EP has a primary specialty listed in PECOS as anesthesiology, radiology or pathology 6 months prior to the first day of the payment adjustments that would otherwise apply. Such an EP may be deemed to qualify for this exception, subject to the 5-year limit that applies to all exceptions under this paragraph.

(5) *Payment adjustments not applicable to hospital-based EPs.* No payment adjustment under paragraphs (d)(1) through (3) of this section may be made in the case of a hospital-based eligible professional, as defined in § 495.4.

[75 FR 44565, July 28, 2010, as amended at 77 FR 54157, Sept. 4, 2012; 77 FR 54157, Sept. 4, 2012; 79 FR 68009, Nov. 13, 2014]

§ 495.104 Incentive payments to eligible hospitals.

(a) *General rule.* A qualifying hospital (as defined in this subpart) must 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 paragraph (d) of this section and the payment formula specified in paragraph (c) 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 2016.

(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.

(iii) The transition factor determined under paragraph (c)(5) of this section.

(2) *Interim and final payments.* CMS uses data on hospital acute care inpatient discharges, Medicare Part A acute care inpatient bed-days, Medicare Part C acute care inpatient bed-days, and total acute care inpatient bed-days from the latest submitted 12-month hospital cost report as the basis for making preliminary incentive payments. Final payments are determined at the time of settling the first 12-month hospital cost report for the hospital fiscal year that begins on or after the first day of the payment year, and settled on the basis of data from that cost reporting period. In cases where there is no 12-month hospital cost report period beginning on or after the first day of the payment year, final payments may be determined and settled on the basis of data from the most recently submitted 12-month hospital cost report.

(3) *Initial amount.* The initial amount is equal to one of the following:

(i) For each hospital with 1,149 acute care inpatient discharges or fewer, \$2,000,000.

(ii) For each hospital with at least 1,150 but no more than 23,000 acute care inpatient discharges, $\$2,000,000 + [\$200 \times (n - 1,149)]$, where n is the number of discharges for the hospital.

(iii) For each hospital with more than 23,000 acute care inpatient discharges, \$6,370,200.

(4) *Medicare share fraction*—(i) *General.* (A) CMS determines the Medicare share fraction for an eligible hospital by using the number of Medicare Part A, Medicare Part C, and total acute care 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—

(I) The number of inpatient-bed-days which are attributable to individuals with respect to whom payment may be

made under Part A, including individuals enrolled in section 1876 Medicare cost plans; and

(2) The number of inpatient-bed-days which are attributable to individuals who are enrolled with a Medicare Advantage organization (as defined in § 422.2 of this chapter).

(B) A denominator which is the product of—

(1) The total number of acute care inpatient-bed-days; and

(2) The total amount of the eligible hospital's charges, not including any charges that are attributable to charity care, divided by the estimated total amount of the hospital's charges.

(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) For 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) For 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) For 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) For hospitals whose first payment year is FY 2015—

(A) $\frac{1}{2}$ for FY 2015; and

(B) $\frac{1}{4}$ for FY 2016.

(d) No incentive payment for non-qualifying hospitals. After the first payment year, an eligible hospital will not receive an incentive payment for any payment year during which it is not a qualifying hospital.

[75 FR 44565, July 28, 2010, as amended at 78 FR 75200, Dec. 10, 2013]

§ 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)(4) 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 adjustment 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 qualifying 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.

[75 FR 44565, July 28, 2010, as amended at 77 FR 54158, Sept. 4, 2012]

§ 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 addressee.

(3) Business phone number.

(4) Such other information as specified by CMS.

(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

§ 495.110

qualifying MA organization's MA EPs and MA-affiliated eligible hospitals.

§ 495.110 Preclusion on administrative and judicial review.

There is no administrative or judicial review under sections 1869 or 1878 of the Act, or otherwise, of the following:

(a) For EPs—

(1) The methodology and standards for determining EP incentive payment amounts;

(2) The methodology and standards for determining the payment adjustments that apply to EPs beginning with 2015;

(3) The methodology and standards for determining whether an EP is a meaningful EHR user, including—

(i) The selection of clinical quality measures; and

(ii) The means of demonstrating meaningful EHR use.

(4) The methodology and standards for determining the hardship exception to the payment adjustments;

(5) The methodology and standards for determining whether an EP is hospital-based; and

(6) The specification of the EHR reporting period, as well as whether payment will be made only once, in a single consolidated payment, or in periodic installments.

(b) For eligible hospitals—

(1) The methodology and standards for determining the incentive payment amounts made to eligible hospitals, including—

(i) The estimates or proxies for determining discharges, inpatient-bed-days, hospital charges, charity charges, and Medicare share; and

(ii) The period used to determine such estimate or proxy;

(2) The methodology and standards for determining the payment adjustments that apply to eligible hospitals beginning with FY 2015;

(3) The methodology and standards for determining whether an eligible hospital is a meaningful EHR user, including—

(i) The selection of clinical quality measures; and

(ii) The means of demonstrating meaningful EHR use.

42 CFR Ch. IV (10–1–15 Edition)

(4) The methodology and standards for determining the hardship exception to the payment adjustments; and

(5) The specification of the EHR reporting period, as well as whether payment will be made only once, in a single consolidated payment, or in periodic installments.

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 section 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.

MA payment adjustment year means—

(1) For qualifying MA organizations that receive an MA EHR incentive payment for at least 1 payment year, calendar years beginning with CY 2015.

(2) For MA-affiliated eligible hospitals, the applicable EHR reporting period for purposes of determining whether the MA organization is subject to a payment adjustment is the federal fiscal year ending in the MA payment adjustment year.

(3) For MA EPs, the applicable EHR reporting period for purposes of determining whether the MA organization is subject to a payment adjustment is the calendar year concurrent with the payment adjustment year.

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 to a Medicare beneficiary.

Payment year means—

(1) For a qualifying MA EP, a calendar year (CY) beginning with CY 2011 and ending with CY 2016; and

(2) For an eligible hospital, a Federal fiscal year (FY) beginning with FY 2011 and ending with FY 2016.

Potentially qualifying MA EPs and potentially qualifying MA-affiliated eligible hospitals are defined for purposes of this subpart in § 495.202(a)(4).

Qualifying MA-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, for which at least two thirds of the Medicare hospital discharges (or bed-days) are of (or for) Medicare individuals enrolled under MA plans, and 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 must 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.

(5) Is not a “hospital-based EP” (as defined in § 495.4 of this part) and in determining whether 90 percent or more of his or her covered professional services were furnished in a hospital setting, only covered professional services furnished to MA plan enrollees of the qualifying MA organization, in lieu of FFS patients, will be considered.

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.

[75 FR 44565, July 28, 2010, as amended at 77 FR 54158, Sept. 4, 2012]

§ 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 2011 (for plan year 2012), 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. “Potentially qualifying MA EPs” and “potentially qualifying MA-affiliated eligible hospitals” are those EPs and hospitals that meet the respective definitions of “qualifying MA EP” and “qualifying MA-affiliated eligible hospital” in § 495.200 but who (or which) are not meaningful users of certified EHR technology.

(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 2012, must make a preliminary identification of MA EPs and MA-affiliated eligible hospitals that the MA organization believes will be qualifying MA EPs and MA-affiliated eligible hospitals for which the organization is seeking incentive payments for the current plan year.

(2) A qualifying MA organization must provide CMS with the following for each MA EP or eligible hospital when reporting under either paragraph (b)(1) or (4) of this section:

(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 or CCN.

(iv) An attestation by MA organization specifying that the MA EP or MA-affiliated eligible hospital meets the eligibility criteria.

(3) When reporting under either paragraph (b)(1) or (4) of this section for purposes of receiving an incentive payment, a qualifying MA organization must also indicate whether more than 50 percent of the covered Medicare professional services being furnished by a qualifying MA EP to MA plan enrollees of the MA organization are being furnished in a designated geographic HPSA (as defined in § 495.100 of this part).

(4) Final identification of qualifying and potentially qualifying, as applicable, MA EPs and MA-affiliated eligible hospitals must be made within 2 months of the close of the payment year or the EHR reporting period that applies to the payment adjustment year as defined in § 495.200.

(5) 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 all MA EPs and MA-affiliated eligible hospitals of the MA organization that the MA organization believes will be either qualifying or potentially qualifying;

(ii) Include information specified in paragraph (b)(2)(i) through (iii) of this section for each professional or hospital; and

(iii) Include an attestation that each professional and hospital either meets or does not meet the EHR incentive payment eligibility criteria.

[75 FR 44565, July 28, 2010, as amended at 77 FR 54158, Sept. 4, 2012]

§ 495.204 Incentive payments to qualifying MA organizations for qualifying MA-EPs and qualifying MA-affiliated eligible 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 2 months of the close of the calendar year, the aggregate annual amount of revenue attributable to providing services that would otherwise be covered as professional services under Part B received by each qualifying MA EP for enrollees in MA plans of the MA organization in the payment year.

(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 section 1848(o)(1)(B) of the Act.

(4) CMS requires the qualifying MA organization to develop a methodological proposal for estimating the portion of each qualifying MA EP's salary or revenue attributable to providing services that would otherwise be covered as professional services under Part B to MA plan enrollees of the MA organization in the payment year. The methodological proposal—

(i) Must be approved by CMS; and

(ii) May include an additional amount related to overhead, where appropriate, estimated to account for the MA-enrollee related Part B practice costs of the qualifying MA EP.

(iii) Methodological proposals must be submitted to CMS by June of the payment year and must be auditable by an independent third-party. CMS will review and approve or disapprove such proposals in a timely manner.

(5) For qualifying MA EPs who are not salaried, qualifying MA organizations may obtain attestations from such qualifying MA EPs (or from entities that the MA EPs are employed by or with which they have a partnership interest) as to the amount of compensation received by such EPs for MA plan enrollees of the MA organization. The organizations may submit to CMS compensation information for each

such MA EP based on such attestations.

(6) For qualifying MA EPs who are not salaried, qualified MA organizations may have qualifying MA EPs (or from entities that the MA EPs are employed by or with which they have a partnership interest) send MA organization compensation information directly to CMS. CMS will use the information provided in this subparagraph or paragraph (b)(5) of this section for no other purpose than to compute the amount of EHR incentive payment due the MA organization.

(c) *Amount payable to qualifying MA organization for qualifying MA-affiliated eligible hospitals.* (1)(i) 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.

(ii) 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) *Potential increase in incentive payment for furnishing services in a geographic HPSA.* In the case of a qualifying MA EP who furnishes more than 50 percent of his or her covered professional services to MA plan enrollees of the qualifying MA organization during a payment year in a geographic HPSA, the maximum amounts referred to in

§ 495.206

42 CFR Ch. IV (10–1–15 Edition)

paragraph (b)(3) of this section are increased by 10 percent.

(f) *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 EHR users 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 6 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.

(5) If an MA EP, or entity that employs an MA EP, or in which an MA EP has a partnership interest, MA-affiliated eligible hospital, or other party contracting with the MA organization, fails to comply with an audit request to produce applicable documents or data, CMS recoups all or a portion of the incentive payment, based on the lack of applicable documents or data.

(g) *Coordination of payment with FFS or Medicaid EHR incentive programs.* (1) If, after payment is made to an MA organization for an MA EP, it is determined that the MA EP is eligible for the full incentive payment under the Medicare FFS EHR Incentive Program or has received a payment under the Medicaid EHR Incentive Program, CMS recoups amounts applicable to the given MA EP from the MA organization's monthly MA payment, or otherwise recoups the applicable amounts.

(2) If, after payment is made to an MA organization for an MA-affiliated eligible hospital, it is determined that

the hospital is ineligible for the incentive payment under the MA EHR Incentive Program, or has received a payment under the Medicare FFS EHR Incentive Program, or if it is determined that all or part of the payment should not have been made on behalf of the MA-affiliated eligible hospital, CMS recoups amounts applicable to the given MA-affiliated eligible hospital from the MA organization's monthly MA payment, or otherwise recoups the applicable amounts.

[75 FR 44565, July 28, 2010, as amended at 77 FR 54158, Sept. 4, 2012]

§ 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) CMS requires a qualifying MA organization that registers MA EPs for the purpose of participating in the MA EHR Incentive Program to notify each of the MA EPs for which it is claiming an incentive payment that the MA organization intends to claim, or has claimed, the MA EP for the current plan year under the MA EHR Incentive Program.

(b) The notice must make clear that the MA EP may still directly receive an EHR incentive payment if the MA EP is entitled to a full incentive payment under the FFS portion of the EHR Incentive Program, or if the MA EP registered to participate under the

Medicaid portion of the EHR Incentive Program and is entitled to payment under that program—in both of which cases no payment would be made for the EP under the MA EHR incentive program.

(c) An attestation by the qualifying MA organization that the qualifying MA organization provided notice to its MA EPs in accordance with this section must be required at the time that meaningful use attestations are due with respect to MA EPs for the payment year.

(d) 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 made under the MA EHR incentive program to a qualifying MA organization.

(e) 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.

(f) 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 § 495.202(b) is provided to CMS.

[75 FR 44565, July 28, 2010, as amended at 77 FR 54159, Sept. 4, 2012]

§ 495.210 Meaningful EHR 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 2 months after the close of a calendar year whether each qualifying MA EP is a meaningful EHR user.

(c) Qualifying MA organizations are required to attest within 2 months after close of the FY whether each qualifying MA-affiliated eligible hospital is a meaningful EHR user.

[75 FR 44565, July 28, 2010, as amended at 77 FR 54159, Sept. 4, 2012]

§ 495.211 Payment adjustments effective for 2015 and subsequent MA payment years with respect to MA EPs and MA-affiliated eligible hospitals.

(a) *In general.* Beginning for MA payment adjustment year 2015, payment adjustments set forth in this section are made to prospective payments (issued under section 1853(a)(1)(A) of the Act) of qualifying MA organizations that previously received incentive payments under the MA EHR Incentive Program, if all or a portion of the MA-EPs and MA-affiliated eligible hospitals that would meet the definition of qualifying MA-EPs or qualifying MA-affiliated eligible hospitals (but for their demonstration of meaningful use) are not meaningful EHR users.

(b) *Adjustment based on payment adjustment year.* The payment adjustment is calculated based on the payment adjustment year.

(c) *Separate application of adjustments for MA EPs and MA-affiliated eligible hospitals.* The payment adjustments identified in paragraphs (d) and (e) of this section are applied separately. Paragraph (d) of this section applies only to qualifying MA organizations that received payment for any MA payment year for qualifying MA EPs under § 495.204. Paragraph (e) of this section applies only to qualifying MA organizations that received payment for any MA payment year for qualifying MA-affiliated eligible hospitals under § 495.204.

(d) *Payment adjustments effective for 2015 and subsequent years with respect to MA EPs.* (1) For payment adjustment year 2015, and subsequent payment adjustment years, if a qualifying MA EP is not a meaningful EHR user during the payment adjustment year, CMS—

(i) Determines a payment adjustment based on data from the payment adjustment year; and

(ii) Collects the payment adjustment owed by adjusting a subsequent year's prospective payment or payments (issued under section 1853(a)(1)(A) of the Act), or by otherwise collecting the payment adjustment, if, in the year of collection, the MA organization does not have an MA contract with CMS.

(2) Beginning for payment adjustment year 2015, a qualifying MA organization that previously received incentive payments must, for each payment adjustment year, report to CMS the following:

[the total number of potentially qualifying MA EPs]/[(the total number of potentially qualifying MA EPs) + (the total number of qualifying MA EPs)].

(3) The monthly prospective payment amount paid under section 1853(a)(1)(A) of the Act for the payment adjustment year is adjusted by the product of—

(i) The percent calculated in accordance with paragraph (d)(2) of this section;

(ii) The Medicare Physician Expenditure Proportion percent, which is CMS's estimate of proportion of expenditures under Parts A and B that are not attributable to Part C that are attributable to expenditures for physicians' services, adjusted for the proportion of expenditures that are provided by EPs that are neither qualifying nor potentially qualifying MA EPs with respect to a qualifying MA organization; and

(iii) The applicable percent identified in paragraph (d)(4) of this section.

(4) *Applicable percent.* The applicable percent is as follows:

(i) For 2015, 1 percent;

(ii) For 2016, 2 percent;

(iii) For 2017, 3 percent.

(iv) For 2018, 3 percent, except, in the case described in paragraph (d)(4)(vi) of this section, 4 percent.

(v) For 2019 and each subsequent year, 3 percent, except, in the case described in paragraph (d)(4)(vi) of this section, the percent from the prior year plus 1 percent. In no case will the applicable percent be higher than 5 percent.

(vi) Beginning with payment adjustment year 2018, if the percentage in paragraph (d)(2) of this section is more than 25 percent, the applicable percent

is increased in accordance with paragraphs (d)(4)(iv) and (v) of this section.

(e) *Payment adjustments effective for 2015 and subsequent years with respect to MA-affiliated eligible hospitals.* (1)(i) The payment adjustment set forth in this paragraph (e) applies if a qualifying MA organization that previously received an incentive payment (or a potentially qualifying MA-affiliated eligible hospital on behalf of its qualifying MA organization) attests that a qualifying MA-affiliated eligible hospital is not a meaningful EHR user for a payment adjustment year.

(ii) The payment adjustment is calculated by multiplying the qualifying MA organization's monthly prospective payment for the payment adjustment year under section 1853(a)(1)(A) of the Act by the percent set forth in paragraph (e)(2) of this section.

(2) The percent set forth in this paragraph (e) is the product of—

(i) The percentage point reduction to the applicable percentage increase in the market basket index for the relevant Federal fiscal year as a result of § 412.64(d)(3) of this chapter;

(ii) The Medicare Hospital Expenditure Proportion percent specified in paragraph (e)(3) of this section; and

(iii) The percent of qualifying and potentially qualifying MA-affiliated eligible hospitals that are not meaningful EHR users. Qualifying MA organizations are required to report to CMS

[the number of potentially qualifying MA-affiliated eligible hospitals] / [(the total number of potentially qualifying MA-affiliated eligible hospitals) + (the total number of qualifying MA-affiliated eligible hospitals)].

(3) The Medicare Hospital Expenditure Proportion for a year is the Secretary's estimate of expenditures under Parts A and B that are not attributable to Part C, that are attributable to expenditures for inpatient hospital services, adjusted for the proportion of expenditures that are provided by hospitals that are neither qualifying nor potentially qualifying MA-affiliated eligible hospitals with respect to a qualifying MA organization.

[77 FR 54159, Sept. 4, 2012]

§ 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 authorize States, at their option, to provide for incentive payments to Medicaid providers for adopting, implementing, or upgrading certified EHR 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 or 1300–1399

Adopt, implement or upgrade means—

(1) Acquire, purchase, or secure access to certified EHR technology capable of meeting meaningful use requirements;

(2) Install or commence utilization of certified EHR technology capable of meeting meaningful use requirements; or

(3) Expand the available functionality of certified EHR technology capable of meeting meaningful use requirements at the practice site, including staffing, maintenance, and training, or upgrade from existing EHR technology to certified EHR technology per the ONC EHR certification criteria.

(4) For payment year 2014, the references to “certified EHR technology” in paragraphs (1) through (3) of this definition are deemed to be references to paragraph (2) of the definition of “Certified EHR Technology” under 45 CFR 170.102 (that is, the definition of “Certified EHR Technology” for FY and CY 2015 and subsequent years).

Children’s hospital means a separately certified children’s hospital, either freestanding or hospital-within-hospital that—

(1) Has a CMS certification number (CCN), (previously known as the Medicare provider number), that has the last 4 digits in the series 3300–3399; or

(2) Does not have a CCN but has been provided an alternative number by CMS for purposes of enrollment in the

§ 495.302

42 CFR Ch. IV (10–1–15 Edition)

Medicaid EHR Incentive Program as a children's hospital and;

(3) 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 certified EHR technology 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 eligible providers.

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 Man-

agement 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, (or a Medicaid or CHIP demonstration project approved under section 1115 of the Act).

(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 (as described at § 495.304(c) through (e)) that is estimated through a numerator and denominator, consistent with the SMHP, and that meets the requirements of § 495.306.

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 (within the most recent calendar year or, as an optional State alternative beginning for payment year 2013, within the 12-month period preceding attestation) 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.

[75 FR 44565, July 28, 2010, as amended at 77 FR 54160, Sept. 4, 2012; 79 FR 52933, Sept. 4, 2014]

§ 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 an EHR incentive payment is limited to the following when consistent with the scope of practice regulations, as applicable for each professional (§§ 440.50, 440.60, 440.100; §§ 440.165, and 440.166):

- (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 (FQHC) led by a physician assistant or a rural health clinic (RHC), that 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, for each year for which the EP seeks an EHR incentive payment, not be hospital-based as defined at § 495.4 of this subpart, and meet one of the following criteria:

(1) Have a minimum 30 percent patient volume attributable to individuals enrolled in a Medicaid program.

(2) Have a minimum 20 percent patient volume attributable to individuals enrolled in a Medicaid program, 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) of this section 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.

(f) *Further patient volume requirements for the Medicaid EP.* For payment year 2013 and all subsequent payment years, at least one clinical location used in the calculation of patient volume must have Certified EHR Technology—

(1) During the payment year for which the EP attests to having adopted, implemented or upgraded Certified EHR Technology (for the first payment year); or

(2) During the payment year for which the EP attests it is a meaningful EHR user.

[75 FR 44565, July 28, 2010, as amended at 77 FR 54160, Sept. 4, 2012]

§ 495.306 Establishing patient volume.

(a) *General rule.* A Medicaid provider must annually meet patient volume requirements of § 495.304, as these requirements are established through the State's SMHP in accordance with the remainder of this section.

(b) *State option(s) through SMHP.* (1) A State must submit through the SMHP the option or options it has selected for measuring patient volume.

(2)(i) A State must select the method described in either paragraph (c) or paragraph (d) of this section (or both methods).

(ii) Under paragraphs (c)(1)(i), (c)(2)(i), (c)(3)(i), (d)(1)(i), and (d)(2)(i) of this section, States may choose whether to allow eligible providers to calculate total Medicaid or total needy individual patient encounters in any representative continuous 90-day period in the 12 months preceding the EP or eligible hospital's attestation or based upon a representative, continuous 90-day period in the calendar year preceding the payment year for which the EP or eligible hospital is attesting.

(3) In addition, or as an alternative to the method selected in paragraph (b)(2) of this section, a State may select the method described in paragraph (g) of this section.

(c) *Methodology, patient encounter*—(1) *EPs*. To calculate Medicaid patient volume, an EP must divide:

(i) The total Medicaid patient encounters in any representative, continuous 90-day period in the calendar year preceding the EP's payment year, or in the 12 months before the EP's attestation; by

(ii) The total patient encounters in the same 90-day period.

(2) *Eligible hospitals*. To calculate Medicaid patient volume, an eligible hospital must divide—

(i) The total Medicaid encounters in any representative, continuous 90-day period in the fiscal year preceding the hospitals' payment year or in the 12 months before the hospital's attestation; by

(ii) The total encounters in the same 90-day period.

(3) *Needy individual patient volume*. To calculate needy individual patient volume, an EP must divide—

(i) The total needy individual patient encounters in any representative, continuous 90-day period in the calendar year preceding the EP's payment year, or in the 12 months before the EP's attestation; by

(ii) The total patient encounters in the same 90-day period.

(d) *Methodology, patient panel*—(1) *EPs*. To calculate Medicaid patient volume, an EP must divide:

(i)(A) The total Medicaid patients assigned to the EP's panel in any representative, continuous 90-day period in either the calendar year preceding the EP's payment year, or the 12 months before the EP's attestation when at least one Medicaid encounter took place with the individual in the 24 months before the beginning of the 90-day period; plus

(B) Unduplicated Medicaid encounters in the same 90-day period; by

(ii)(A) The total patients assigned to the provider in that same 90-day period with at least one encounter taking place with the patient during the 24 months before the beginning of the 90-day period; plus

(B) All unduplicated patient encounters in the same 90-day period.

(2) *Needy individual patient volume*. To calculate needy individual patient volume an EP must divide—

(i)(A) The total Needy Individual patients assigned to the EP's panel in any representative, continuous 90-day period in the either the calendar year preceding the EP's payment year, or the 12 months before the EP's attestation when at least one Needy Individual encounter took place with the individual in the 24 months before the beginning of the same 90-day period; plus

(B) Unduplicated Needy Individual encounters in the same 90-day period, by

(ii)(A) The total patients assigned to the provider in that same 90-day period with at least one encounter taking place with the patient during the 24 months before the beginning of the 90-day period, plus

(B) All unduplicated patient encounters in the same 90-day period.

(e) For purposes of this section, the following rules apply:

(1) A Medicaid encounter means services rendered to an individual on any one day where:

(i) Medicaid (or a Medicaid demonstration project approved under section 1115 of the Act) paid for part or all of the service.

(ii) Medicaid (or a Medicaid demonstration project approved under section 1115 of the Act) paid all or part of the individual's premiums, co-payments, and cost-sharing.

(iii) The individual was enrolled in a Medicaid program (or a Medicaid demonstration project approved under section 1115 of the Act) at the time the billable service was provided.

(2) For purposes of calculating hospital patient volume, both of the following definitions in paragraphs (e)(2)(i) and (e)(2)(ii) of this section may apply:

(i) A Medicaid encounter means services rendered to an individual per inpatient discharge when any of the following occur:

(A) Medicaid (or a Medicaid demonstration project approved under section 1115 of the Act) paid for part or all of the service.

(B) Medicaid (or a Medicaid demonstration project approved under section 1115 of the Act) paid all or part of the individual's premiums, co-payments, and/or cost-sharing.

(C) The individual was enrolled in a Medicaid program (or a Medicaid demonstration project approved under section 1115 of the Act) at the time the billable service was provided.

(ii) A Medicaid encounter means services rendered in an emergency department on any 1 day if any of the following occur:

(A) Medicaid (or a Medicaid demonstration project approved under section 1115 of the Act) paid for part or all of the service.

(B) Medicaid (or a Medicaid demonstration project approved under section 1115 of the Act) paid all or part of the individual's premiums, co-payments, and cost-sharing.

(C) The individual was enrolled in a Medicaid program (or a Medicaid demonstration project approved under section 1115 of the Act) at the time the billable service was provided.

(3) For purposes of calculating needy individual patient volume, a needy patient encounter means services rendered to an individual on any 1 day if any of the following occur:

(i) Medicaid or CHIP (or a Medicaid or CHIP demonstration project approved under section 1115 of the Act) paid for part or all of the service.

(ii) Medicaid or CHIP (or a Medicaid or CHIP demonstration project approved under section 1115 of the Act) paid all or part of the individual's premiums, co-payments, or cost-sharing.

(iii) The individual was enrolled in a Medicaid program (or a Medicaid demonstration project approved under section 1115 of the Act) at the time the billable service was provided.

(iv) The services were furnished at no cost; and calculated consistent with § 495.310(h).

(v) The services were paid for at a reduced cost based on a sliding scale determined by the individual's ability to pay.

(f) *Exception.* A children's hospital is not required to meet Medicaid patient volume requirements.

(g) *Establishing an alternative methodology.* A State may submit to CMS for

review and approval through the SMHP an alternative from the options included in paragraphs (c) and (d) of this section, so long as it meets the following requirements:

(1) It is submitted consistent with all rules governing the SMHP at § 495.332.

(2) Has an auditable data source.

(3) Has received input from the relevant stakeholder group.

(4) It does not result, in the aggregate, in fewer providers becoming eligible than the methodologies in either paragraphs (c) and (d) of this section.

(h) *Group practices.* Clinics or group practices will be permitted to calculate patient volume at the group practice/clinic level, but only in accordance with all of the following limitations:

(1) The clinic or group practice's patient volume is appropriate as a patient volume methodology calculation for the EP.

(2) There is an auditable data source to support the clinic's or group practice's patient volume determination.

(3) All EPs in the group practice or clinic must use the same methodology for the payment year.

(4) The clinic or group practice uses the entire practice or clinic's patient volume and does not limit patient volume in any way.

(5) If an EP works inside and outside of the clinic or practice, then the patient volume calculation includes only those encounters associated with the clinic or group practice, and not the EP's outside encounters.

[75 FR 44565, July 28, 2010, as amended at 77 FR 54160, Sept. 4, 2012]

§ 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, implementation or upgrade 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

42 CFR Ch. IV (10–1–15 Edition)

§ 495.310 Medicaid provider incentive payments.

(a) *Rules for Medicaid EPs.* The Medicaid EP's incentive payments are subject to all of the following limitations:

(1) *First payment year.* (i) For the first payment year, payment under this subpart may not exceed 85 percent of the maximum threshold of \$25,000, which equals \$21,250.

(ii) [Reserved]

(iii) An EP may not begin receiving payments any later than CY 2016.

(2) *Subsequent annual payment years.*

(i) For subsequent payment years, payment may not exceed 85 percent of the maximum threshold of \$10,000, which equals \$8,500.

(ii) [Reserved]

(iii) Payments after the first payment year may continue for a maximum of 5 years.

(iv) Medicaid EPs may receive payments on a non-consecutive, annual basis.

(v) No payments may be made after CY 2021.

(3) *Maximum incentives.* In no case may a Medicaid EP participate for more than a total of 6 years, and 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 payment is limited as follows:

(i) The maximum payment in the first payment year is further reduced by two-thirds, which equals \$14,167.

(ii) The maximum payment in subsequent payment years is further reduced by 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) *Limitation to only one EHR incentive program.* An EP may only receive an incentive payment from either Medicare or Medicaid in a payment year, but not both.

(d) *Exception for EPs to switch programs.* An EP may change his or her EHR incentive payment program election once, consistent with § 495.10 of this part.

(e) *Limitation to one State only.* A Medicaid EP or eligible 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 FY 2016, and after FY 2016, a hospital may not receive an incentive payment unless it received an incentive payment in the prior fiscal year.

(6) Prior to FY 2016, payments can be made to an eligible hospital on a non-consecutive, annual basis for the fiscal year.

(7) A multi-site hospital with one CMS Certification Number is considered one hospital for purposes of calculating payment.

(8) The aggregate EHR hospital incentive amount calculated under paragraph (g) of this section is determined by the State from which the eligible hospital receives its first payment year incentive. If a hospital receives incentive payments from other States in subsequent years, total incentive payments received over all payment years of the program can be no greater than

the aggregate EHR incentive amount calculated by the initial State.

(g) *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 the most recent continuous 12-month period selected by the State, but ending before the federal fiscal year that serves as the first payment year. The discharge-related amount is the sum of the following, with acute-care inpatient discharges over the 12-month period and based upon the total acute-care inpatient discharges for the eligible hospital (regardless of any source of payment):

(1) For the first through 1,149th acute-care inpatient discharge, \$0.

(2) For the 1,150th through the 23,000th acute-care inpatient discharge, \$200.

(3) For any acute-care inpatient 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, acute-care inpatient 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 acute-care inpatient-bed-days which are attributable to Medicaid individuals; and

(B) The estimated number of acute-care 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 acute-care 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 acute-care inpatient-bed-days under paragraph (g)(2)(i) of this section, a State may not include estimated acute-care inpatient-bed-days attributable to individuals with respect to whom payment may be made under Medicare Part A, or acute-care 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 provider'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.

§ 495.312

42 CFR Ch. IV (10–1–15 Edition)

(i) *Deeming.* In the absence of the data necessary, with respect to an eligible hospital the amount described in paragraph (g)(2)(ii)(B) of this section 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 in the payment year.

(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 reassign 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 reassigning annual payments and includes information about the verification mechanism the State will use to ensure that the reassignment 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]

[75 FR 44565, July 28, 2010, as amended at 77 FR 54161, Sept. 4, 2012]

§ 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's role.* (1) Except as specified in paragraph (c)(2) of this section, the

State determines the provider's eligibility for the EHR incentive payment under subparts A and D of this part and approves, processes, and makes timely payments using a process approved by CMS.

(2) At the State's option, CMS conducts the audits and handles any subsequent appeals, of whether eligible hospitals are meaningful EHR users on the States' behalf.

(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 verification of eligibility for the payment year.

(2) *Medicaid eligible hospitals.* States disburse payments consistent with the Federal fiscal year on a rolling basis following verification of eligibility for the payment year.

[75 FR 44565, July 28, 2010, as amended at 77 FR 54162, Sept. 4, 2012]

§ 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 payment year, it has adopted, implemented, or upgraded certified EHR technology, as defined in § 495.302.

(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 § 495.352 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, or 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 demonstrating that they are meaningful users 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)(i) Subject to § 495.332, the State may propose a revised definition for Stage 1 of meaningful use of certified EHR technology, subject to CMS prior approval, but only with respect to the following objectives:

(A) Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, research or outreach.

(B) Capability to submit electronic data to immunization registries or immunization information systems and actual submission except where prohibited, and according to applicable law and practice.

(C) Capability to submit electronic data on reportable (as required by State or local law) lab results to public health agencies and actual submission except where prohibited according to applicable law and practice.

(D) Capability to submit electronic syndromic surveillance data to public health agencies and actual submission except where prohibited and according to applicable law and practice.

(ii) Subject to § 495.332, the State may propose a revised definition for Stage 2 of meaningful use of certified EHR technology, subject to CMS prior approval, but only with respect to the following objectives:

(A) Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, research, or outreach.

(B) Capability to submit electronic data to immunization registries or immunization information systems, except where prohibited, and in accordance with applicable law and practice.

(C) Capability to submit electronic reportable laboratory results to public health agencies, except where prohibited, and in accordance with applicable law and practice.

(D) Capability to provide electronic syndromic surveillance data to public health agencies, except where prohibited, and in accordance with applicable law and practice.

(E) Capability to identify and report cancer cases to a public health central

§ 495.318

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

(F) Capability to identify and report specific cases to a specialized registry (other than a cancer registry), except where prohibited, and in accordance with applicable law and practice.

(e) State failure to submit the required reports to CMS may result in discontinued or disallowed funding.

[75 FR 44565, July 28, 2010, as amended at 77 FR 54162, Sept. 4, 2012]

§ 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 HHS, 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) Is 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

42 CFR Ch. IV (10–1–15 Edition)

initiate planning and implementation activities in support of Medicaid provider incentive payments encouraging the adoption and meaningful 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 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 of Health and Human Services, prior to release of the request for proposal or prior to execution of a contract.

(3) For contract amendments, unless specifically exempted by HHS, before execution of the contract amendment, involving contract cost increases exceeding \$100,000 or contract time extensions of more than 60 days.

(4) The State Medicaid HIT plan.

(c) Failure to submit any of the information specified in paragraph (b) of this section to the satisfaction of HHS may result in disapproval or suspension of project funding.

(d) A State must obtain prior written approval from HHS 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 FFP.

If the HHS 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, suspension would

occur in the same manner as 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 FFP for failure to provide access to information.

(a) HHS 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 health information technology (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) and other requirements included in ARRA.

(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 beneficiaries 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; and

(iv) 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 or eligible hospital is a provider who meets patient volume consistent with the criteria in § 495.304 and § 495.306 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 a methodology for verifying such information.

(6) For ensuring that at least one clinical location used for the calculation of the EP's patient volume has Certified EHR Technology during the payment year for which the EP is attesting.

(c) *Monitoring and validation.* Subject to paragraph (g) of this section, for monitoring and validation of information States must include the following:

(1) A description of the process in place for ensuring that, because of CMS' and the States' oversight responsibilities, all provider information for attestations including meaningful use, efforts to adopt, implement, or upgrade and any information added to the CMS Single Provider Repository including all information related to patient volume, NPI, Tax identification number (TIN), 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 EHR reporting period, and that they have adopted, implemented, or upgraded certified EHR technology 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 their participation year and a methodology for verifying such information.

(6) A list of the specific actions planned to implement the 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 by the State 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.

(8) A description of the process in place to ensure that no amounts higher than 90 percent of FFP will be claimed by the State for administrative expenses in administering the certified EHR technology incentive payment program and a methodology for verifying such information.

(9) A description of the process and methodology for ensuring and verifying 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 incentive payment reassignments 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 EP 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.* For payments, States 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 the methodology for verifying such information.

(4) The process in place and the methodology for verifying that information is available in order to ensure that Medicaid EHR incentive payments are made for no more than a total of 6 years; that no EP or eligible hospital begins receiving payments after 2016; that incentive payments cease after 2021; and that an eligible hospital does not receive incentive payments after FY 2016 unless the hospital received an incentive payment in the prior fiscal year.

§ 495.334

42 CFR Ch. IV (10–1–15 Edition)

(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.

(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.

(7) The process in place to provide for the timely and accurate payment of incentive payments to EPs and eligible hospitals, including the timeframe 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(g).

(2)(i) A revised definition of meaningful use of certified EHR technology consistent with § 495.4 and § 495.316(d)(2) of this part.

(ii) Any revised definition of meaningful use may not require additional functionality beyond that of certified EHR technology and conform with CMS guidance on Stage 1. See also § 495.316(d)(2).

(g) *Optional—signed agreement.* At the State's option, the State may include a signed agreement indicating that the State does all of the following:

(1) Designates CMS to conduct all audits and appeals of eligible hospitals' meaningful use attestations.

(2) Is bound by the audit and appeal findings described in paragraph (g)(1) of this section.

(3) Performs any necessary recoupments if audits (and any subsequent appeals) described in paragraph (g)(1) of this section determine that an eligible hospital was not a meaningful EHR user.

(4) Is liable for any FFP granted to the State to pay eligible hospitals that, upon audit (and any subsequent appeal) are determined not to have been meaningful EHR users.

[75 FR 44565, July 28, 2010, as amended at 77 FR 54162, Sept. 4, 2012]

§ 495.334 [Reserved]

§ 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.

(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 including:

(1) Planned annual payment amounts;

(2) Total of planned payment amounts; and

(3) Calendar year of each planned annual payment amount.

(4) 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.

§ 495.338 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.

§ 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 is required to submit the HIT IAPD Updates 12 months from the date of the last CMS approved HIT IAPD and must contain the following:

(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

§ 495.344

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.

[75 FR 44565, July 28, 2010, as amended at 77 FR 54162, Sept. 4, 2012]

§ 495.344 Approval of the State Medicaid HIT plan, the HIT PAPD and update, the HIT IAPD and update, and the annual HIT IAPD.

HHS will not approve the State Medicaid HIT plan, HIT PAPD and update, HIT-IAPD and update, or annual IAPD if any of these documents do not include all of the information required under this subpart.

§ 495.346 Access to systems and records.

The State agency must allow HHS 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

42 CFR Ch. IV (10-1-15 Edition)

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 sub agreements.

(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 offer or 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 offer or 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 pro-

curement 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 2 CFR part 376.

(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 HHS 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.

§ 495.352 Reporting requirements.

Each State must submit to HHS 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 beneficiaries or subbeneficiaries 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 CFR 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.* HHS reserves a royalty-free, non-exclusive, and irrevocable license to reproduce, publish or otherwise use and to authorize others to use for Federal government purposes, the software, modifications, and documentation designed, developed or installed with FFP under this Subpart.

(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.

§ 495.364

42 CFR Ch. IV (10–1–15 Edition)

(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 inpatient or emergency room setting.

(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 § 495.312, 495.314, and § 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.

(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 that Medicaid EHR incentive payments are made for no more than 6 years; that no EP or eligible hospital begins receiving payments after 2016; that incentive payments cease after 2021; and that an eligible hospital does not receive incentive payments after FY 2016 unless the hospital received an incentive payment in the prior fiscal 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.

[75 FR 44565, July 28, 2010, as amended at 75 FR 81887, Dec. 29, 2010]

§ 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 § 455.15 and § 455.21 of this chapter, 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.* For any forms on which a provider submits information necessary to the determination of eligibility to receive EHR payments, the State must obtain a statement that meets the following requirements:

(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

§ 495.370

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 deter-

42 CFR Ch. IV (10–1–15 Edition)

mination 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.

(d) This section does not apply in the case that CMS conducts the audits and handles any subsequent appeals under § 495.312(c)(2) of this part.

[75 FR 44565, July 28, 2010, as amended at 77 FR 54161, Sept. 4, 2012]

PART 498—APPEALS PROCEDURES FOR DETERMINATIONS THAT AFFECT PARTICIPATION IN THE MEDICARE PROGRAM AND FOR DETERMINATIONS THAT AFFECT THE PARTICIPATION OF ICFs/IID AND CERTAIN NFs IN THE MEDICAID PROGRAM

Subpart A—General Provisions

Sec.

498.1 Statutory basis.

498.2 Definitions.

498.3 Scope and applicability.

498.4 NFs subject to appeals process in part 498.

498.5 Appeal rights.

498.10 Appointment of representatives.

498.11 Authority of representatives.

498.13 Fees for services of representatives.

498.15 Charge for transcripts.

498.17 Filing of briefs with the ALJ or Departmental Appeals Board, and opportunity for rebuttal.

Subpart B—Initial, Reconsidered, and Revised Determinations

498.20 Notice and effect of initial determinations.

498.22 Reconsideration.

498.23 Withdrawal of request for reconsideration.

498.24 Reconsidered determination.

498.25 Notice and effect of reconsidered determination.

Subpart C—Reopening of Initial or Reconsidered Determinations

498.30 Limitation on reopening.