Outline of the Medicare and Medicaid Programs; Electronic Health Record Incentive Program (Meaningful Use) Under the Health Information Technology for Economic and Clinical Health Act (Title XIII of the American Recovery and Reinvestment Act of 2009) FINAL RULE

Federal Register **Volume 75 Page No.**	**Section-by-Section Content**
1	Department of Health and Human Services Office of the Secretary 42 CFR 412, 413, 422, and 495 Electronic Health Records Incentive Program Agency: Centers for Medicare and Medicaid Services (CMS) Announced: Tuesday, July 13, 2010 Published: Tuesday, July 13, 2010 Summary: Final rule to implement the provisions of the American Recovery and Reinvestment Act of 2009 (ARRA, Pub. L. 111-5) that provide incentive payments to eligible professionals (EPs) and eligible hospitals participating in Medicare and Medicaid programs that adopt and meaningfully use certified electronic health record (EHR) technology.
13	**I. Background**
13	I. A. Overview of the HITECH Programs Created by the American Recovery and Reinvestment Act of 2009 • Summarizes the incentive program mandated within ARRA and notes related rulemaking on EHR standards and certification
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18	II. A. Definitions Across the Medicare FFS, Medicare Advantage, and Medicaid Programs
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33	II. A. 2. Definition of Meaningful Use
52	II. A. 2. c. Stage 1 Criteria for Meaningful Use • Ability of EPs, eligible hospitals, or CAHs to meet all Stage 1 meaningful use objectives and their associated measures • Reduced requirements both in number and in the thresholds of the associated measures and provide some additional flexibility as well. • Establishes a core set of objectives with associated measures and a menu set of objectives with associated measures • In order to qualify as a meaningful EHR user, an EP, eligible hospital, or CAH must successfully meet the measure for each objective in the core set and all but five of the objectives in the menu set o One limitation: All EPs and hospitals must choose at least one of the population and public health measures to demonstrate as part of the menu set • Ability of certain EP, eligible hospital, or CAH to meet all Stage 1 meaningful use objectives given established scopes of practice o Modifies each objective and measure to indicate when there is an option to report that the objective/measure is inapplicable because of no patients or no or insufficient number of actions that would allow calculation of the measure o Exclusions to meaningful use objectives/measures are specific to each objective/measure o Providers wishing to claim that an objective/measure is inapplicable to them would need to meet the specified exceptions o Attestation that an objective in the core set is inapplicable would remove the objective from consideration when determining whether an EP, eligible hospital, or CAH is a meaningful EHR user o For objectives in the menu set, such an attestation would also remove the objective from consideration when determining whether an EP, eligible hospital, or CAH is a meaningful EHR user and the provider must satisfy the remaining applicable number of objectives • EPs practicing in multiple practices o To be a meaningful EHR user an EP must have 50 percent or more of their patient encounters during the EHR reporting period at a practice/location or practices/locations equipped with certified EHR technology. o An EP for who does not conduct 50 percent of their patient encounters in any one practice/location would have to meet the 50 percent threshold through a combination of practices/locations equipped with certified EHR technology • Burden created by the measures associated with Stage 1 meaningful use o Rationale for changing the way compliance with the measures is calculated o The following objectives and their associated measures are limited to patients whose records are maintained using certified EHR ▪ Use CPOE ▪ Generate and transmit permissible prescriptions electronically (eRx) ▪ Record and chart changes in vital signs ▪ Record smoking status for patients 13 years old or older

	▪ Record advance directives for patients 65 years old or older ▪ Incorporate clinical lab test results into certified EHR technology as structured data ▪ Provide patients with an electronic copy of their health information (including diagnostic test results, problem list, medication lists, medication allergies), upon request ▪ Provide patients with an electronic copy of their discharge instructions at time of discharge, upon request ▪ Provide clinical summaries for patients for each office visit ▪ Send reminders to patients per patient preference for preventive/follow-up care ▪ Perform medication reconciliation at relevant encounters and each transition of care ▪ Provide summary care record for each transition of care and referral • Meaningful use relationship to certified EHR technology • Relationship between a Stage 1 meaningful use objective and its associated measure and selected major changes from the NPRM o Use CPOE (CORE) ▪ Order can be entered by any licensed healthcare professional into the medical record per state, local and professional guidelines ▪ Limited to medication orders in Stage 1 ▪ For hospitals, includes orders in the ED ▪ Explains the reasoning behind reporting based on "unique patients" ▪ Transmission of the order is not included in the objective or the associated measure for Stage 1 ▪ The ability to calculate the measure is included in certified EHR technology exclusion ▪ If an EP writes fewer than one hundred prescriptions during the EHR reporting period they would be excluded from this requirement as described previously o Implement drug-drug, drug-allergy (CORE), drug-formulary checks (MENU) ▪ Separates drug-drug and drug-allergy from formulary checks ▪ must have at least one formulary that can be queried ▪ must be available for the entire reporting period o Maintain an up-to-date problem list of current and active diagnoses based on ICD-9-CM-CM or SNOMED CT® (CORE) ▪ Does not require coding at the time of the encounter, can be done later ▪ Removes references to standards (provided in standards rules) o Generate and transmit permissible prescriptions electronically (eRx) (CORE) o Maintain active medication list (CORE) o Maintain active medication allergy list (CORE) o Record the following demographics: preferred language, insurance type, gender, race and ethnicity, and date of birth and additionally for hospitals date and cause of death in the event of mortality (CORE) ▪ Must be recorded as structured data o Record and chart changes in the following vital signs: height, weight and

	blood pressure and calculate and display body mass index (BMI) for ages 2 and over; plot and display growth charts for children 2–20 years, including BMI. (CORE) ▪ Must be recorded as structured data ▪ Exclusion may apply depending on patient age and/or scope of practice of provider o Record smoking status for patients 13 years old or older (CORE) ▪ Must be recorded as structured data o Record advance directives (MENU) ▪ Was not a requirement in the NPRM ▪ Applicable to hospital patients 65 years and older o Incorporate clinical lab-test results into EHR as structured data (MENU) o Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, research, and outreach (MENU) o Report ambulatory quality measures to CMS (or, for EPs seeking the Medicaid incentive payment, the states) (CORE) o Send reminders to patients per patient preference for preventive/follow-up care (MENU) ▪ Applies to patients age 65 and older or 5 years or younger o Document a progress note for each encounter—rationale for not including this as part of meaningful use is provided. This is not in the final rule. o Implement five clinical decision support rules relevant to specialty or high clinical priority, including for diagnostic test ordering, along with the ability to track compliance with those rule. ▪ Scaled back to one clinical decision support rule (CORE) o Submit claims electronically to public and private payers ▪ Removed from final rule for Stage 1—will move to Stage 2 o Check insurance eligibility electronically from public and private payers ▪ Removed from final rule for Stage 1—will move to Stage 2 o Provide patients with an electronic copy of their health information (including diagnostic test results, problem list, medication lists, allergies, discharge summary (hospitals), procedures (hospitals)), upon request (CORE) ▪ Must be electronic and in human readable form and in accordance with the standards specified in the ONC final rule ▪ When responding to patient requests for information, the EP, eligible hospital, or CAH should accommodate patient requests in accordance with 45 C.F.R. 164.524, Access of individuals to protected health information ▪ Limits the information that must be provided electronically to that information that exists electronically in or is accessible from the certified EHR technology maintained by or on behalf of the EP, eligible hospital, or CAH ▪ As per 45 C.F.R. 164.524, may withhold information that may be deemed harmful to the patient ▪ Subject to the withholding described above, an EP, eligible hospital, or CAH should provide a patient with all of the health information they have

	available electronically ▪ The charging of fees for electronic copies is governed by the HIPAA Privacy Rule at 45 C.F.R. 164.524(c)(4) (which only permits HIPAA covered entities to charge an individual a reasonable, cost-based fee for a copy of the individual's health information) ▪ Cost for electronic copies are expected by CMS to be minimal since ability to generate the copy is included in certified EHR technology ▪ Fees that a HIPAA CE "may impose on an individual for an electronic copy of the individual's health information will be addressed in upcoming rulemaking" ▪ The associated measure extends the time to provide information t o the patient from 48 hours in the NPRM to 3 business days in the final regulation. The threshold was reduced from 80 percent to 50 percent of patients requesting a copy ▪ Calculation of the measure will require entering the patient's request into the certified EHR technology ▪ Third-party requests (other than those from or by the patient's family or representative) are not included in the numerator or denominator when calculating the measure ▪ EPs, eligible hospitals, and CAHs are to provide the information pursuant to the reasonable accommodations for patient preference under 45 C.F.R.164.522(b). The media could be any electronic form such as patient portal, PHR, CD, USB fob, etc. o Provide patients with an electronic copy of their discharge instructions at time of discharge, upon request (hospitals, CORE) o Provide patients with timely electronic access to their health information (including lab results, problem list, medication lists, medication allergies) within four business days of the information being available to the EP (EPs, MENU) o Provide clinical summaries for patients for each office visit (CORE) ▪ Can be provided through a PHR, patient portal on the website, secure e-mail, electronic media such as CD or USB fob, or printed copy. The after-visit clinical summary contains an updated medication list, laboratory and other diagnostic test orders, procedures, and other instructions based on clinical discussions that took place during the office visit ▪ Must be provided within 3 days of visit o Use certified EHR technology to identify patient-specific education resources and provide those resources to the patient, if appropriate (MENU) o Capability to exchange key clinical information among providers of care and patient authorized entities electronically (CORE) o Perform medication reconciliation at relevant encounters and each transition of care (MENU) o Provide summary care record for each transition of care or referral (MENU) ▪ Could send an electronic or paper copy of the summary care record directly to the next provider or could provide it to the patient to deliver to the next provider, if the patient can reasonably expected to do so

	▪ Certified EHR technology would be used to generate the summary of care record and to document that it was provided to the patient or receiving provider o Capability to submit electronic data to immunization registries and actual submission where required and accepted (MENU) o Capability to provide electronic submission of reportable (as required by state or local law) lab results to public health agencies and actual submission where it can be received (MENU) ▪ Limited to hospitals ▪ Modified to "Capability to submit electronic data on reportable (as required by state or local law) lab results to public health agencies and actual submission in accordance with applicable law and practice" o Capability to provide electronic syndromic surveillance data to public health agencies and actual transmission according to applicable law and practice. (MENU) ▪ Applies to EPs and Hospitals ▪ Modified to "Capability to submit electronic syndromic surveillance data to public health agencies and actual submission in accordance with applicable law and practice." o Protect electronic health information created or maintained by the certified EHR technology through the implementation of appropriate technical capabilities (CORE)
221	• Core objectives and measures are listed in "Table 2: Stage 1 Meaningful Use Objectives and Associated Measures Sorted by Core and Menu Set"
231	II. A. 3. Sections 4101(a) and 4102(a)(1) of HITECH Act: Reporting on Clinical Quality Measures Using EHR by EPs, Eligible Hospitals and CAHs
231	II. A. 3. a. General • Overview of the third requirement of meaningful use—using certified EHR technology to submit information for the EHR reporting period on clinical quality measures and other measures specified by the Secretary.
231	II. A. 3. b. Requirements for the Submission of Clinical Quality Measures by EPs, Eligible Hospitals and CAHs • Provides definition of "clinical quality measures." • CMS is adopting only those electronic measure specifications that are posted on the CMS website as of the date of display of this final rule. • States must describe in their State Medicaid HIT Plans how they plan to accept data from Medicaid providers who seek to demonstrate meaningful use.
239	II. A. 3. c. Statutory Requirements and Other Considerations for the Selection of Clinical Quality Measures for Electronic Submission by EPs, Eligible Hospitals and CAHs
239	II. A. 3. c. (1) Statutory Requirements

	• Describes statutory requirements for selecting quality measures for the program. • Technical specifications for clinical quality measures are developed and finalized through a sub-regulatory process. • Describes how CMS plans to align the program quality measure reporting requirements with other CMS quality measure reporting requirements (i.e., PQRI and RHQDAPU).
247	II. A. 3. c. (2) Other Considerations • Describes additional considerations applied to the selection of clinical quality measures for electronic submission under the Medicare and Medicaid EHR incentive program. • Table 4 (p. 249) contains 4 clinical quality measures included in this final rule that are also part of the CHIPRA initial measure set to align the two programs and create efficiencies for states and pediatric providers. • Describes the look-back period for capturing clinical quality measures. • Describes the process for defining clinical quality measure exclusion parameters and process for reporting measures in which exclusions apply.

254	II. A. 3. d. Clinical Quality Measures for EPs
	• CMS removed measures that do not have electronic specifications by the date of display of this final rule.
	• Table 5 (pp. 261–268) contains 44 clinical quality measures that were *proposed* for submission by Medicare or Medicaid EPs for the 2011 and 2012 payment year but *removed* from the final rule.
	• CMS included only those clinical quality measures that can be automatically calculated by a certified EHR technology.
	• Table 6 (pp. 272–282) contains 44 clinical quality measures for submission by Medicare or Medicaid EPs for the 2011 and 2012 payment year.
	  o 3 of the 44 clinical quality measures are designated as *core* measures
	  o 3 of the 44 clinical quality measures are designated as *alternate core* measures

283	II. A. 3. e. Clinical Quality Measures Reporting Criteria for EPs • Table 7 (pp. 287–288) contains the core measure set for EPs that will be required for Stage 1. • CMS expanded the core measure set to include three alternate measures based on commenter feedback. • CMS requires all EPs to report the 3 core measures. Insofar as the denominator for one or more of the core measures is zero, EPs will be required to report results for up to 3 alternate core measures. • The EP will not be excluded from reporting any core or alternate clinical quality measure because the measure does not apply to the EP's scope of practice or patient population. • There is no requirement that the EP have any particular number of patients in the denominator, which could be zero as calculated by the EHR.

	• CMS removed the requirement for EPs to report on specialty measure groups. • EPs must report on 6 total measures: 3 core measures (substituting alternate core measures where necessary) and 3 additional measures (other than the core and alternate core measures) selected from table 6.
292	II. A. 3. f. Clinical Quality Measures for Electronic Submission by Eligible Hospitals • Table 8 (pp. 296–299) contains 20 clinical quality measures that were ***proposed*** for submission by Medicare or Medicaid eligible hospitals for the 2011 and 2012 payment year but ***removed*** from the final rule. • Table 9 (pp. 299–300) contains 8 ***proposed alternate*** Medicaid clinical quality measures for Medicaid eligible hospitals that were ***removed*** from the final rule. • CMS included only those clinical quality measures where there are electronic specifications as of the date of display of this final rule. • Table 10 (pp. 303–305) contains 15 clinical quality measures for submission by eligible hospitals and CAHs for the 2011 and 2012 payment year. • Eligible hospitals and CAHs will report numerators, denominators, and exclusions, even if one or more values as displayed by their EHR is zero.
309	II. A. 3. g. Potential Measures for EPs, Eligible Hospitals and CAHs in Stage 2 and Subsequent Years • Summary of public comments related to proposed new clinical quality measures for Stage 2 and subsequent years. • Table 11 (pp. 315–318) contains proposed new clinical quality measures for EPs. • Table 12 (pp. 319–321) contains proposed new clinical quality measure topics for EPs.
321	II. A. 3. h. Reporting Method for Clinical Quality Measures for 2011 and Beginning with the 2012 Payment Years
321	II. A. 3. h. (1) Reporting Method for 2011 Payment Year • CMS finalizes requirements for EPs and eligible hospitals to attest to the numerators, denominators, and exclusions in their first payment year for the required clinical quality measures.
327	II. A. 3. h. (2) Reporting Method Beginning in 2012 • Describes alternative options for electronic submission of clinical quality measure results beginning in 2012. • Medicare EPs, eligible hospitals, and CAHs will be required to report the required clinical quality measures information electronically using certified EHR technology via one of three methods. • For Medicaid, information will be submitted to states as directed by the states. • CMS will post technical requirements for submission on its website for Medicare EPs on or before July 1, 2011, and for Medicare eligible hospitals and CAHs on or before April 1, 2011.

339	II. A. 3. i. Alternative Reporting Methods for Clinical Quality Measures • Summary of comments received regarding the proposed alternative reporting methods for clinical quality measures.
341	II. A. 3. j. Reporting Period for Reporting Clinical Quality Measures • Summary of comments received regarding the proposed EHR reporting period for EPs, eligible hospitals, and CAHs.
342	II. A. 4. Demonstration of Meaningful Use
343	II. A. 4. a. Common Methods of Demonstration in Medicare and Medicaid • CMS adopts a common method for demonstrating meaningful use in both the Medicare and Medicaid EHR incentive programs.
343	II. A. 4. b. Methods for Demonstration of the Stage 1 Criteria of Meaningful Use • Description of the requirements that EPs, eligible hospitals, and CAHs must demonstrate to satisfy each of the objectives and associated measures of the core set and menu set for Stage 1 criteria of meaningful use. • Leaves open the possibility for CMS and /or States to test options to utilize existing and emerging HIT products and infrastructure capabilities (e.g., registries, etc.) to satisfy other objectives of the meaningful use definition.
349	II. A. 5. Data Collection for Online Posting, Program Coordination, and Accurate Payments
349	II. A. 5. a. Online Posting • Describes requirements for the Secretary to list, in an easily understandable format, the names and other relevant data of EPs, eligible hospitals, and CAHs who are meaningful EHR users under the Medicare FFS program on an Internet website.
350	II. A. 5. b. Program Election between Medicare FFS/MA and Medicaid for EPs • Describes the circumstances in which EPs may change their incentive payment election during the EHR incentive program. • CMS provides clarification in response to public comments on non-consecutive payments.
355	II. A. 5. c. Data to be Collected • Describes the Medicare and Medicaid administrative data CMS will collect to fulfill requirements of online posting, avoidance of duplication of incentive payments, and ensure accurate and timely incentive payments.
358	II. A. 6. Hospital-based Eligible Professionals • Clarifies the definition of hospital-based eligible professionals based on the Continuing Extension Act of 2010.

367	II. A. 7. Interaction with other Programs • Describes interactions between the Medicare EHR incentive program and the E-prescribing Incentive Program authorized by MIPAA. • EPs (or group practices) who accept a Medicare EHR incentive payment for a given year will be excluded from being eligible for the E-prescribing Incentive Program payment for that same year. • EPs receiving a Medicaid EHR incentive payment would remain eligible for the Medicare MIPAA E-Prescribing Incentive Program payment.
368	II. B. Medicare-Fee-for-Service Incentives
368	II. B. 1. Incentive Payments for Eligible Professionals • CMS provides for an incentive payment amount, subject to an annual limit, equal to 75 percent of the estimated Medicare allowed charge for professional services during the incentive period (up to 5 years). • No payment after 2016.
369	II. B. 1. a. Definitions • "Eligible professional" relates to "physician" to mean (as dictated by legislation) the following five types of professionals, each of which must be legally authorized to practice under state law: doctor of medicine or osteopathy, a doctor of dental surgery or dental medicine, a doctor of podiatric medicine, a doctor of optometry, or a chiropractor. • "Professional services" are services furnished by an EP for which payment is made under, or is based on, the Medicare physician fee schedule. • This section also covers "allowed charges" and the period of time used to define these charges.
373	II. B. 1. b. Incentive Payment Limits • This section remains as proposed and sets the limits for the EP incentive payments over the 5 years: o $15,000 (or $18,000 if the first payment years is 2011 or 2012), o $12,000 for the EP's second payment year, o $8,000 for the EP's third payment year, o $4,000 for the EP's fourth payment year, o $2,000 for the EP's fifth payment year, and o $0 for any succeeding year. • However, if an EP does not qualify to receive an EHR-related incentive payment prior to 2015, then the EP will not qualify for any payment.
374	II. B. 1. c. Increase in Incentive Payment for EPs who Predominately Furnish Services in a Geographic Health Professional Shortage Area (HPSA). • This section remains as proposed: an EP who predominantly furnishes services in an HPSA designated area by the secretary will have the annual incentive increased by 10 percent. • "Predominately" means greater than 50 percent and will be determined over a 1-

	year period from January 1 to December 31. The incentive payment will be based on the EP's estimated allowed charges for the relevant payment year based on claims received no later than 2 months after the year ends. • The section also covers how payments will be made.
380	II. B. 1. d. Form and Timing of Payment • CMS notes it will provide the incentive payment as a single consolidated payment. • This payment can be reassigned by the EP to its employer or an entity with which it has a valid employment agreement or contract. • Payments will be made as soon as Medicare ascertains an EP has demonstrated meaningful use for the applicable period. • The issue of the anti-kickback statute was raised in comments, and CMS states it cannot determine if the statue is in play since situations differ. • While the proposed rule stands for this section, there may be situations where the EP's Social Security Number can be used instead of a tax identification number.
388	II. B. 1. e. Payment Adjustment Effective in CY 2015 and Subsequent Years for EPs who are not Meaningful Users of Certified EHR Technology • CMS is retaining its penalty process of reducing reimbursement for EPs who are not meaningful EHR users during a relevant year starting in calendar 2014 (and therefore affecting payment in CY2015). Payment is reduced by 1 percent, for this and subsequent years if the EP continues to not be a EHR meaningful user, up to 5 percent reduction. • There is also a hardship exception on a case-by-case basis.
390	II. B. 2. Incentive Payments for Hospitals
390	II. B. 2. a. Definition of Eligible Hospital for Medicare • CMS is retaining this section as proposed in spite of a large number of contrary comments. The incentive program will only apply to the 50 states and the District of Columbia. In addition, hospitals that meet the definition of a "subsection D" hospital will be paid on the basis of their CMS Certification Number.
397	II. B. 2. b. Incentive Payment Calculation for Eligible Hospitals: Initial Amount • CMS is keeping the proposed payment amounts based in part on the number of acute care discharges (defined in the discussion). • Discharges will relate to the hospitals fiscal year for Medicare. • The final rule is changed with regard to the timing of cost reports, and CMS is adopting the policy that it will employ discharge and other data from a hospital's most recently filed 12-month cost report for determining the hospital's preliminary incentive payment once the hospital has qualified as a meaningful user. The precise timing of payments, especially during the first payment year, may be affected by other factors such as the timeline for implementing the requisite systems to calculate and disburse payments. • New cost reporting forms are being developed to cover the program.

	• The final rule is changes with regard to final incentive payments (not interim) and CMS is adopting the policy that it will determine final incentive payments at the time of settling the 12-month cost report for the hospital fiscal year that begins after the beginning of the payment year, and to be settled on the basis of the hospital discharge and other data from that cost reporting period. • CMS acknowledges it did not address circumstances of non-standard cost reporting period and provides information on how it will address such reports.
406	II. B. 2. c. Incentive Payment Calculation for Eligible Hospital: Medicare Share • The final rule is amended to take account of the changes above in "b" and the cost reports that must be modified to accommodate meaningful use. • The final rule also reflects errors on the identification of data in the NPRM and how CMS will calculate bed days and the cost report sources it will use.
419	II. B. 2. d. Incentive Payment Calculation for Eligible Hospitals: Charity Care and Charges • CMS piggy-backs on the clarifications and cost report identification used above as it applies to charity care and the formulas used. Essentially, nothing was changed in this section beyond this identification.
427	II. B. 2. e. Incentive Payment Calculation for Eligible Hospitals: Transition Factor • This section merely describes the formula for payment with regard to the transition factor called for under the law.
429	II. B. 2. f. Duration and Timing of Incentive Payments • CMS notes that its NPRM was incorrect and should have stated that hospitals "whose first payment year is FY2015 may receive such payments for FY2015 through 2016"; otherwise the rule stays as proposed.
432	II. B. 2. g. Incentive Payment Adjustment Effective in FY2015 and Subsequent Years for Eligible Hospitals who are not Meaningful EHR Users • The CMS proposed rule indicated that future rule making would address the penalties for hospitals that did not become meaningful users and accordingly there is no proposal at this time.
433	II. B. 3. Incentive Payments for Critical Access Hospitals
434	II. B. 3. a. Definition of CAHs for Medicare • CMS makes no changes and will identify CAHs for payment by their CMS Certification Number.
434	II. B. 3. b. Current Medicare Payment of Reasonable Cost for CAHs • No changes were made, since the section merely describes how CAHs are paid under Medicare.

436	II. B. 3. c. Changes made by the HITECH Act • No changes were made to this section, and its stands as proposed.
438	II. B. 3. d. Incentive Payment Calculation for CAHs • CMS provides clarification on the costs that will be included in the payment made to CAHs, and the fact that there will be a lump sum rather than a sum that reflects on going depreciation. CMS notes minor changes to the cost report as commented on above and also notes that CAHs need to work with their Medicare contractors with regard to some of the data that will be needed.
446	II. B. 3. e. Reduction of Reasonable Cost Payment in FY 2015 and Subsequent Years for CAHs that are not Meaningful EHR Users • CMS is maintaining the proposed rule approach to develop reductions in cost reimbursement to CAHs that are not meaningful users by FY 2015 and beyond and supplies these calculations. CMS notes that there will be the potential not to be penalized under a case by case request and analysis. • CMS clarifies that CAHs can appeal the payment amount determined by CMS.
448	II. B. 4. Process for Making Incentive Payments Under the Medicare FFS Program
448	II. B. 4. a. Incentive Payments to EPs • CMS reviews the proposal from the NPRM, including the note that EPs must choose between Medicare and Medicaid. It also repeats the issues of relationships with employers or similar entities. • CMS announces that the program will not be carried out through carriers or MACs as originally proposed; rather, National Level Repository, using data from the Integrated Data Repository, will be making the payment. This is a single contractor who will be making the payments; otherwise the system for payment will be as proposed.
453	II. B. 4. b. Incentive Payments to Eligible Hospitals • CMS review the proposal from the NPRM and previous comment relative to information flowing from the cost report. • CMS announces that while the hospital EHR incentive payments will be calculated by the FIs/MACS, a single payment contractor will be employed to facilitate funds control and payment.
458	II. B. 4. c. Incentive Payments to CAHs • Like other hospitals, FIs/MACs will receive the required information from CAHs, but a single contractor will disburse the incentive payment.
461	II. B. 4. d. Payment Accounting Under Medicare • CMS reiterates that it will conduct selected compliance reviews of EPs, eligible hospitals, and qualified CAHs who register for the incentive programs or receive payments. • Medicare FFS EPs and eligible hospitals will need to maintain evidence of

	qualification to receive incentive payments for 10 years after the date they register for the incentive program.
461	II. B. 5. Preclusion of Administrative and Judicial Review • This section introduces preclusion of administrative and judicial review for the various entities that can apply for meaningful use incentive programs.
463	II. C. Medicare Advantage (MA) Organization Incentive Payments
463	II. C. 1. Definitions
463	II. C. 1. a. Qualifying MA Organization • HITECH references the Public Health Service Act to define a qualifying MA organization: a federally qualified health maintenance organization, a recognized HMO under state law, or an organization regulated for solvency under state law in the same manner and to the same extent as an HMO. • CMS believes that any MA organization offering HMO plans meets the Act's definition, because the MA approval process requires state authorization. • A sponsoring organization will attest for any MA organization offering coordinated care MA plans and other MA plans types. • The date by which MA organizations must identify themselves to CMS has been extended to the bidding deadline in June 2011 (for plan year 2012).
465	II. C. 1. b. Qualifying MA Eligible Professional • EPs must be employed by the qualifying MA organization or, through contract with them, furnish at least 80 percent of the organization's Medicare patient care services (as measured in revenue). • The EP further must furnish at least 80 percent of his or her professional services covered under Medicare to enrollees (as measured in revenue). • The EP must furnish on average at least 20 hours per week of patient care services, which may include both Medicare and non-Medicare patients. The MA organization will attest to this criteria being met. • The final rule adds a specific hospital-based MA EP exclusion to the definition.
473	II. C. 1. c. Qualifying MA-Affiliated Eligible Hospital • Eligible hospitals are under common corporate governance with a qualifying MA organization and serve individuals enrolled under MA plans offered by the organization. • Incentive payments will be made under the Fee-for-Service program because of the complexity in assigning payment between the programs, which is calculated on the share of inpatient bed days attributable to different Medicare plans.
476	II. C. 2. Identification of Qualifying MA Organizations, MA EPs, and MA-Affiliated Eligible Hospitals • Describes the process and requirements through which MA organizations identify themselves to HHS and indicate potentially qualifying MA EPs.

	• The final rule changes the proposed deadlines:
	  o Preliminary identification of MA EPs and MA-affiliated hospitals for payment year 2011 must occur by the bidding deadline in June 2011.
	  o Final identification must occur with 60 days of the close of the payment year.

481	II. C. 3. Computation of Incentives to Qualifying MA Organizations for MA EPs and Hospitals • Describes the method for calculating payment for EPs and affiliated hospitals, which includes lump sum payments, duplicate payments, annual limits, and payment cycle. • MA organizations should maintain evidence of compliance with the program for 10 years following payment, as CMS intends to conduct selected compliance reviews.
496	II. C. 4. Timeframe for Payment • The first possible incentive payments related to EPs will be made in early 2012, because CMS will first compute payments under the FFS program to avoid duplication. • Payments for MA-affiliated hospitals will occur at the same time as payments under FFS. • The MA organization will be paid on the same schedule for all of its qualifying EPs.
500	II. C. 5. Avoiding Duplicate Payment • As described in II.C.4, CMS will first compute payments for EPs under the FFS program before calculating payments under MA in order to avoid duplication. • As described in II.C.1.c, payments for MA-affiliated hospitals will be made under the FFS program to avoid potential duplication.
502	II. C. 6. Meaningful User Attestation • Each MA organization will attest in a form and manner to be specified by CMS that its EPs and affiliated hospitals are meaningful EHR users. • Attestation must be made each year. • MA organizations will not be required to submit clinical quality measures for either EPs or affiliated hospitals per §1848(o)(2)(B) of the Act; CMS believes that all qualifying MA organizations will offer MA coordinated care plans and thus be submitting the HEDIS data set under that program. • CMS invites comment on proposals for reporting measures that overlap with existing MA quality reporting programs in regards §1848(o)(2)(B)(iii) and §1886(n)(3)(B)(iii).
511	II. C. 7. Posting Information on the CMS Website • Describes the information CMS will post on the MA organizations receiving incentive payments.

511	II. C. 8. Limitation on Review • There will be no administrative or judicial review of the method or standards for determining payment.
512	II. C. 9**.** Conforming Changes • Describes the necessary conforming changes to the regulation's text
513	II. C. 10. Payment Adjustment and Future Rulemaking • In future rulemaking CMS will develop standards on payment adjustments for EPs and affiliated hospitals that have not become meaningful users
516	II. D. Medicaid Incentives
516	II. D. 1. Overview of Health Information Technology in Medicaid • Provides a brief overview of the Medicaid program and the requirements to report to Congress. • Identification of challenges experienced by Medicaid that are different from other EHR adoption and implementations.
518	II. D. 2. General Medicaid Provisions • Identifies the options for the states: o 90 percent FFP for state expenditures related to the administration of an EHR incentive program for certain Medicaid providers that are adopting, implementing, or upgrading and meaningfully using certified EHR technology; or o 100 percent FFP for state expenditures for those incentive payments.
518	II. D. 3. Identification of Qualifying Medicaid EPs and Eligible Hospitals
518	II. D. 3. a. Overview • Only certain Medicaid providers will be eligible for incentive payments.
519	II. D. 3. b. Program Participation • Describes the requirements of meeting the EP definition: o physicians, o dentists, o certified nurse-midwives, o nurse practitioners, and o physician assistants practicing in an o Federally Qualified Health Center (FQHC) or Rural Health Clinic (RHC) that is so led by a physician assistant. • States that acute care and children's hospitals are the only two types of institutional providers potentially eligible for Medicaid incentive payments. • Adds Critical Access Hospital (CAH) in the definition of acute care hospital.

527	II. D. 3. c. Medicaid Professionals Program Eligibility • Describes the patient volume requirements for meeting eligibility • Medicaid patient volume • Medicaid "needy individual" patient volume
530	II. D. 3. d. Calculating Patient Volume Requirements • Describes the methods by which patient volume is determined for EPs and those EPs with practices predominantly in an FHQC or RHC. • CMS is allowing for some flexibility in the approach toward calculating but must be submitted and approved before use. This will occur on a case-by-case basis. • CMS revises the definition of EPs to clarify additional scope of practice requirements.
548	II. D. 3. e. Entities Promoting the Adoption of Certified EHR Technology • Incentive payments must generally be made directly to EPs, with the exception to permit payment of incentive payments to "entities promoting the adoption of certified EHR technology," as designated by the state. o Definition of "promoting" is provided. o Regional Extension Centers may be included in the definition as well. • The entity must not retain more than 5 percent of the payment for costs unrelated to certified EHR technology (and support services including maintenance and training) that is for, or is necessary for, the operation of the technology.
550	II. D. 4. Computation of Amount Payable to Qualifying Medicaid EPs and Eligible Hospitals
550	II. D. 4. a. Payment Methodology for EPs • Describes the calculation for paying incentives to EPs and eligible hospitals • EPs could receive as much as $29,000 in funding from other sources (other than state or local governments). • Cap of incentive payment is $25,000 in the first year. However, payment to EPs is only 85 percent of net average allowable costs; therefore, the maximum incentive for the first year would be $21,250. • Cap of incentive payment is $10,000 for each of the 5 subsequent years. However, payment to EPs is only 85 percent of net average allowable costs; therefore, the maximum incentive for the each subsequent year is $8,500. • States must submit to CMS for review and approval a description of their process and methodology for verifying payment incentives in State Medicaid Health Information Technology plans. • Payments for EPs are in alignment with the calendar year as well as the Medicare program. • Medicaid EPs are *not* required to participate on a consecutive annual basis; however, the last year an EP may begin receiving payments is 2016, and the last year the EP can receive payments is 2021.

569	II. D. 4. b. Payment Methodology for Eligible Hospitals • Hospitals receiving a Medicaid incentive payment must receive payments on a consecutive, annual basis after the year 2016. Prior to 2016, Medicaid incentive payments to hospitals can be made on a non-onsecutive, annual basis. • Unlike Medicaid EPs, who must waive rights to duplicative Medicare incentive payments, hospitals *may receive incentive payments from both Medicare and Medicaid*, contingent on successful demonstration of meaningful use and other requirements under both programs.
581	II. D. 4. c. Alternative and Optional Early State Implementation to Make Incentive Payments for Adopting, Implementing, or Upgrading Certified EHR Technology • States will not be permitted to make payments until January 2011. • States must have a State Medicaid Health Information Technology Plan approved by CMS before making any payments to EPs and eligible hospitals.
582	II. D. 4. d. Process for Making and Receiving Medicaid Incentive Payments • Medicaid EPs who practice in multiple states must choose only one state from which to receive Medicaid incentive payments in each payment year. • Medicaid EPs will enroll in the program through the single provider election repository. Once an EP selects the Medicaid EHR incentive program, states must have a system for reporting and tracking necessary information to qualify an EP for an incentive payment. • Medicaid providers in their second participation year (or in their first payment year if they are qualifying based on meaningful use) shall demonstrate meaningful use over a 90-day reporting period. In their third and subsequent years they must demonstrate for 12 months.
585	II. D. 4. e. Avoiding Duplicate Payment • To ensure against duplicate incentive payments, three conditions are required: (1) knowing which EHR incentive program a provider has selected; (2) uniquely identifying each provider participating in each incentive program; and (3) ensuring that each state has access to the information on which EPs or hospitals intend to receive incentive payments from another state or from the Medicare program.
586	II. D. 4. f. Flexibility for EPs to Alternate Between Medicare and Medicaid EHR Incentive Programs One Time • Medicaid EPs can make *one EHR incentive program election change* prior to the 2015 payment year, and not to permit any switching after the 2014 payment year.
586	II. D. 4. g. One State Selection • EPs and hospitals with multi-state Medicaid practice locations annually pick one state from which to receive incentive payments. A provider will not be able to receive incentive payments from more than one state in the same year. • Medicaid EPs and hospitals could annually change the state they select when they re-attest to program requirements.

588	II. D. 5. Single Provider Election Repository and State Data Collection
588	II. D. 6. Collection of Information Related to the Eligible Professional's National Provider Identifier and the Tax Identification Number • EPs would not be permitted to require a state to divide payments among different practices or practice locations based upon group tax identification numbers.
590	II. D. 7. Activities Required to Receive Incentive Payments
590	II. D. 7. a. General Overview
590	II. D. 7. b. Definitions Related to Certified EHR Technology and Adopting, Implementing or Upgrading Such Technology • (1) Certified EHR Technology • (2) Adopting, Implementing or Upgrading
596	II. D. 7. c. Other General Terminology • There is no EHR reporting period for adopting, implementing, or upgrading in Medicaid providers' first participation year, if they qualify based on Adopt, Implement, Upgrade, and there is a 90-day reporting period for both the first year that a Medicaid provider demonstrates meaningful use.
601	II. D. 7. d. Quality Measures • CMS intends to update its definition of meaningful use biennially, and it expects that its updated Stage 2 definition will include additional Medicaid clinical quality measures to be reported from EHRs.
604	II. D. 8. Overview of Conditions for States to Receive Federal Financial Participation (FFP) for Incentive Payments and Implementation Funding • States must develop an HIT Planning Advance Planning Document, a State Medicaid Health Information Technology Plan, and an HIT Implementation Advance Planning Document.
631	II. D. 9. Financial Oversight, Program Integrity and Provider Appeals • States will be responsible for estimating the expenditures for the Medicaid EHR incentive program on the state's quarterly budget estimate reports. • These reports will be used as the basis for Medicaid quarterly grant awards that will be advanced to the state for the Medicaid EHR incentive program. • The state submits the form electronically to CMS via the Medicaid and State CHIP Budget and Expenditure System.

639	**III. Collection of Information Requirements**
640	III. A. ICRs Regarding Demonstration of Meaningful Use Criteria (§495.8) • CMS discusses how it estimated burdens for the assorted activities related to meaningful use; for example, attestation, completing the required registration processes, and the actual demonstration of meaningful use.
702	**IV. Regulatory Impact Analysis (RIA)**
702	IV. A. Overall Impact • A RIA must be prepared for any rule of economic significant effect ($100 million or more in any 1 year), and this rule falls under that requirement. • CMS notes that this final rule addresses the impacts related to the actions taken by EPs, eligible hospitals, or CAHs to demonstrate meaningful use of certified EHR technology, including purchasing or developing in-house certified EHR technology or EHR technology modules. Therefore, there is uncertainty in these estimates, including the status of the sustainable growth rate (SGR) formula. • CMS takes the approach of two scenarios. The high scenario presumes that roughly a decade from now, nearly 100 percent of hospitals and 70 percent of EPs will be meaningful users. The low scenario presumes that only 95.6 percent of hospitals and 36 percent of EPs will be meaningful users. Accordingly, for several covered reasons, CMS estimates that under the high scenario transfer payments will be $27.4 billion, while low would be $9.7 billion.
708	IV. B. Regulatory Flexibility Analysis • Again the RFA requirement is met since most providers are considered small. • CMS acknowledges that all providers of Medicare or Medicaid will be impacted since there are penalties as well as incentives. • CMS believes that the advantages and gains from EHRs will compensate for the initial expenditures.
709	IV. B. 1. Number of Small Entities • 624,000 healthcare entities are estimated as covered. Of those, 94.71 percent will be EPs, 0.8 percent will be hospitals, and 4.47 percent will be MAO physicians or hospitals. • EPs will spend approximately $54,000 to purchase and implement a certified EHR and $10,000 annually for ongoing maintenance. CMS provides its rational from the Congressional Budget Office.
711	IV. B. 2. Alternatives Considered • CMS reviews the limitations on flexibility the ARR-HITECH presented and notes its attempt to come up with a program designed to encourage more widespread adoption of certified EHR technology.

712	IV. B. 3. Conclusion • CMS states it believes that the object of the Regulatory Flexibility Act to minimize burden on small entities are met by the final rule.
713	IV. C. Small Rural Hospitals • CMS notes the RIA requirements for small rural hospitals and again provides its opinion that they will benefit from this final rule in the long run.
714	IV. D. Unfunded Mandates Reform Act • CMS notes that the rule imposes no substantial mandate on states. • CMS also reiterates that the program is voluntary for States and State offer the incentives at their option. • CMS further reiterates that the federal government will fund 90 percent of the State's related administrative costs, providing controls on the total State outlay.
715	IV. E. Federalism • Again CMS estimates the limited impact on states.
716	IV. F. Anticipated Effects
716	IV. G. HITECH Impact Analysis
716	IV. G. 1. Need for Regulation • ARRA-HITECH 2009
717	IV. G. 2. Alternatives Considered • Limited discretion on the part of CMS.
717	IV. G. 3. Background and Assumptions • CMS provides its assumptions on the number of entities that will apply for the incentive payments and the anticipated financial impacts on these entities as well as entities that fail to become meaningful users.
719	IV. G. 4. Industry Costs and Adoption Rates • Again CMS provides estimates for the cost of purchase, implementation, and maintenance of EHRs for EPs and eligible hospitals.
724	IV. G. 5. Medicare Incentive Program Costs • CMS then provides the anticipated costs to the program (including the incentive payments), noting the additional EPs added by recent Congressional action on some hospital-related physicians, using its high and low scenarios.
739	IV. G. 6. Medicaid Incentive Program Costs • Similarly, costs are estimated from the Medicaid program using costs and savings and the two scenarios for EPs and hospitals.

744 IV. G. 7. Benefits for all EPs and all Eligible Hospitals

- CMS summarizes the benefits of EHRs in EPs and hospitals including cost reductions, patient safety, administrative savings, and so forth.

745 IV. G. 8. Benefits to Society

- Likewise CMS provides an overview of the benefits to society.

746 IV. G. 9. General Considerations

- CMS notes that the estimates to the HITECH Act provisions are based on the economic assumption underlying the president's 2011 budget.
- Estimates for the Medicare incentive payment are excluded from the determination of MA capitation benchmarks.
- CMS believes that the incentive payments and the prospect of eventual payment penalties will result in the great majority of hospitals implementing certified EHR technology in the early years of the incentive program. It expects that a steadily growing proportion of practices will implement certified EHR technology over the next 10 years, even in the absence of the Medicare incentives.

749 IV. G. 10. Summary

TABLE 51: Estimated EHR Incentive Payments and Benefits Impacts on the Medicare and Medicaid Programs of the HITECH EHR Incentive Program. (Fiscal Year) – (in billions) Low Scenario

Fiscal Year	Medicare Eligible		Medicaid Eligible		Total
	Hospitals	Professionals	Hospitals	Professionals	
2011	$0.2	$0.2	$0.4	$0.2	$1.0
2012	$0.9	$1.0	$0.1	$0.4	$2.4
2013	$1.1	$0.9	$0.4	$0.4	$2.8
2014	$1.2	$0.6	$0.4	$0.4	$2.6
2015	$0.5	-$0.1	$0.5	$0.5	$1.4
2016	$0.6	-$0.6	$0.7	$0.6	$1.3
2017	$0.3	-$1.3	$0.8	$0.5	$0.3
2018	-$0.2	-$1.6	$0.4	$0.4	-$1.0
2019	-$0.1	-$1.6	$0.1	$0.3	-$1.3
TOTAL	**$4.6**	**-$2.5**	**$3.8**	**$3.8**	**$9.7**

Table 39: Estimated EHR Incentive Payments and Benefits Impacts on the Medicare and Medicaid Programs of the HITECH EHR Incentive Program. (Fiscal Year) – (in billions) High Scenario

	Medicare Eligible		Medicaid Eligible		
Fiscal Year	Hospitals	Professionals	Hospitals	Professionals	Total
2011	$0.5	$0.6	$0.8	$0.9	$2.8
2012	$2.1	$2.3	$0.3	$1.1	$5.8
2013	$2.2	$2.0	$0.9	$1.0	$6.1
2014	$1.9	$1.3	$0.7	$0.9	$4.8
2015	$1.8	$0.7	$0.6	$1.1	$4.2
2016	$1.2	$0.1	$0.5	$1.1	$2.9
2017	$0.5	-$0.5	$0.4	$0.9	$1.3
2018	—	-$0.8	$0.2	$0.6	0.0
2019	—	-$0.8	—	$0.3	-$0.5
TOTAL	**$10.1**	**$5.0**	**$4.3**	**$8.0**	**$27.4**

750 IV. G. 11. Explanation of Benefits and Savings Calculation

- CMS notes that in its analysis it assumed "that benefits to the program would accrue in the form of savings to Medicare, through the Medicare EP payment adjustments. Expected qualitative benefits, such as improved quality of care better health outcomes, and the like, are still unable to be qualified at this time."

750 IV. H. Accounting Statement

- In accordance with the provisions of the Executive Order, this final rule was reviewed by the Office of Management and Budget

TABLE 40: Accounting Statement: Classification of Estimated Expenditures CYs 2010 through 2019

		Category: Transfers	
Annualized Monetized		Low Estimate	High Estimate
	7%	1,147.9 million	3,102.2 million
	3%	1,038.7 million	2,902.4 million
From Whom to Whom		Federal government to eligible professionals and hospitals.	
		Category: Industry Costs Associated with Reporting Requirements	
		Low Estimate	High Estimate
		626.62 million	652.35 million
From Whom to Whom		Private industry.	
		Category: Other Industry Costs	
Annualized Monetized		Low Estimate	High Estimate
	7%	TBD	TBD
	3%	TBD	TBD
From Whom to Whom		Private industry.	