Meaningful Use
CMS Proposed Rule
Overview

On December 30, 2009, the HHS Office of the National Coordinator for Health Information Technology (ONC) and the Centers for Medicare and Medicaid Services (CMS) held a press conference to announce two long-awaited rule proposals. The first rule was the Medicare and Medicaid Programs, Electronic Health Record Incentive Program – commonly called the Meaningful Use rule. The second rule– an Interim Final Rule (IFR) that adopts an initial set of standards, implementation specifications, and certification criteria for electronic health record (EHR) technology e necessary to achieve Meaningful Use.

This Overview covers the Meaningful Use Notice of Proposed Rule Making (NPRM), which was posted on December 30 in draft form. This overview is not intended to be an analysis of the document but to provide information on the rule as it was displayed by CMS and ONC. As with any overview or analysis, readers should thoroughly read the official *Federal Register* published document once it is available. Page numbers referenced in this Overview refer to the 12/30/2009 version (http://www.federalregister.gov/OFRUpload/OFRData/2009-31217_PI.pdf). Readers should note that in this NPRM draft references and titles vary and are not consistent. This will be corrected in the published *Federal Register* NPRM. This overview will be revised in the future when the rule is officially published; currently expected on January 13, 2010.

The Meaningful Use rule is delivered by CMS as a notice of proposed rulemaking (NPRM) and covers 42 CFR Parts 412, 413, 422, and 495. It is referenced as either CMS-0033P or RIN 0938-AP78. The rule comes about from the passage of the American Recovery and Reinvestment Act of 2009 (ARRA), as signed into law (P.L. 111-5) on February 17, 2009.

We expect the official proposed rule will be published on January 13, 2010 in the *Federal Register,* with an allowable 60 days for public comment. ONC, in collaboration with CMS, has indicated that a final rule is not expected until late spring/early summer 2010. AHIMA is preparing for comment submission within the required timeframe.

This NPRM asks continually for comments, therefore readers should not assume this NPRM draft as final. Readers should make comments to CMS as requested and as appropriate to your situation.

Highlights:

- The "Medicare and Medicaid Programs: Electronic Health Record Incentive Program (Meaningful Use) NPRM draft was released by CMS on 12/30/2009.
- The official NPRM will be published January 13, 2010, in the *Federal Register* http://www.access.gpo.gov/su_docs/fedreg/a100113c.html (not effective until 1/13/2010).
- The Meaningful Use (MU) NPRM outlines the necessary criteria to become a "meaningful user" in order to qualify for the incentive programs. .
- The incentive programs begin in FY2011 or CY2011; however, some providers could qualify for payment under Medicare in 2010.
- There are three "stages" for the MU program and this NPRM sets the rules for the first stage and requests comments for the second and third stages. While qualified providers must go through all stages, they do not necessarily have to begin the first stage in FY or CY2011.
- Meaningful use only has to occur for a 90-day period in the first stage.

- The NPRM sets the criteria for MU and the measures that will be used. Initial attestation as to reporting on these measures will not be a direct electronic submission from the EHR early in the first stage. The proposed criteria are the minimum criteria – states could potentially add additional criteria under their Medicaid program.
- In addition to the MU criteria and HIT functionality measurement reporting, there are also clinical quality measure reporting requirements.
- This NPRM details the payment mechanisms and processes for both incentive payments as well as penalties (in later years).
- Under the Medicaid program, providers treating patients from more than one state may only receive incentive payments from one state.
- CMS indicates that there could be significant changes in the final rule given the opportunity the public has to comment on this proposed rule.

The NPRM begins (p 2) with instructions for sending in comments, CMS personnel that can be contacted for further information, and supplementary information (p 5) that covers acronyms and a table of contents. Since the document does not have page numbers associated with the table of comments, this Overview will identify the table headings for reference to the pages.

I. Background (p16):

A. Overview: A background of the HITECH programs created by ARRA is included here. The document suggests that HITECH should be considered as both the ARRA sections on Medicare and Medicaid incentives as well as Title XIII of ARRA – the Health Information Technology for Economic and Clinical Health Act (HITECH). The background also clarifies terminology referenced in the document including "Meaningful Use," "meaningful use of certified EHR technology," (which is the subject of the Interim Final Rule (IFR) issued on the same date), and "certified EHR technology" which is also to be defined by ONC. **CMS suggests that readers review not only this NPRM, but also the ONC IFR.**

This section also identifies an acronym used throughout the document – "EP" which stands for eligible professional.

B. Statutory Basis: The second section (p 18) is "Statutory Basis for Medicare and Medicaid Programs," which covers the multitude of statutes that make up Medicare and Medicaid reimbursement requirements and will be affected by this new rule. CMS also highlights some of the HITECH sections that provide implementation funding for the states outside of that identified in the ARRA section on Medicare and Medicaid.

II: Provisions of the Proposed Regulations (p 20) provide:

A. Definitions Across the Medicare Fee For Service, Medicare Advantage, and Medicaid Programs

1. Common definitions will be used in the regulation across the three affected federal programs – Medicare Fee For Service program (FFS), Medicare Advantage (MA), and Medicaid Programs

– and how they impact EHR incentives (incentive EHR programs). The common definitions (p 21) include:

a. **Certified Electronic Health Record (EHR) Technology (p 22)** – defined by ONC.
b. **Qualified Electronic Health Record (p 23)** – defined by ONC.
c. **Payment Year (p 23)—**also called "year of payment." This section briefly discusses user eligibility.
d. **First, Second, Third, Fourth, Fifth, and Sixth Payment Year (p 25)**
e. **EHR Reporting Period (p 25):** an initial definition for eligibility for incentives (long explanation). This section also notes when CMS is considering the start of the incentive program noting that a final rule will not be forthcoming until at least April and will have a 60 day period before it takes effect.
f. **Meaningful EHR User (p 32)**

Each definition includes how the definition was determined and for what purpose. This is detail that will not be included in the rule itself.

2. **Definition of Meaningful Use (p 32) provides:**
   a. **The background behind the development of this definition and references (p 32**): which includes the statute requirements: (1) use of certified EHR technology in a meaningful manner (for example electronic prescribing); (2) that the certified EHR technology is connected in a manner that provides for the electronic exchange of health information to improve the quality of care; and (3) that in using certified EHR technology, the provider submits to the Secretary information on clinical quality measures and such other measures selected by the Secretary. CMS lists the input that it received in coming to the definition.
   b. **The common definition of Meaningful Use under Medicare and Medicaid (p 36):** CMS notes that it found no reason for the definition to differ under the various programs (Medicare and Medicaid) covered, however, this is a minimum definition and state Medicaid programs could add to it with HHS approval. CMS also explains that this will be a moving definition dependant on which year a respective EP or eligible hospital is in. CMS also briefly covers who is potentially eligible for what Medicare or Medicaid program.
   c. **Consideration in Defining Meaningful Use (p 39):** CMS notes that "certified EHR technology used in a meaningful way by providers is one piece of a broader HIT infrastructure needed to reform the health care system and improve healthcare quality, efficiency, and patient safety." To do this CMS is defining meaningful use through the creation of criteria that will be required in three stages with the criteria updated biennially such that stage 2 criteria would be proposed by the end of 2011 and the Stage 3 criteria by the end of 2013. This last stage would bring the healthcare system to the "ultimate goal" of the legislation. CMS then lists (p 40) the goals for each of the three stages and requests comments on this approach. Finally, CMS describes the method it is proposing to track the stage of a provider through this system, which can be reflected in the table below copied from CMS.

TABLE 1: Stage of Meaningful Use Criteria by Payment Year

First Payment Year	Payment Year				
	2011	2012	2013	2014	2015 +**
2011	Stage 1	Stage 1	Stage 2	Stage 2	Stage 3
2012		Stage 1	Stage 1	Stage 2	Stage 3
2013			Stage 1	Stage 2	Stage 3
2014				Stage 1	Stage 3
2015+*					Stage 3

* Avoids payment adjustments only for EPs in the Medicare EHR Incentive Program.
** Stage 3 criteria of meaningful use or a subsequent update to the criteria if one is established through rulemaking.

d. **Stage 1 Criteria for Meaningful Use (p 47):** CMS proceeds to go into detail (pp 47 - 103) on each of the criteria and HIT functionality measures it is proposing for EPs and hospitals and encourages comments on the proposed criteria. CMS notes its concern that certain providers may have difficulty meeting one or more of the proposed objectives for Stage 1, and solicits comments on whether this is the case. Commenters are asked to identify the objective and associated measures that may "prove out of reach for certain provider types or specialties, and to suggest specific objective criteria they could use to determine whether an objective and associate measures is appropriate for different provider types or specialists. Readers should pay attention to this detail, but in the interest of space we are duplicating below a table of these requirements as provided by CMS (pp 103-108)

TABLE 2: Stage 1 Criteria for Meaningful Use

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

Health Outcomes Policy Priority	Care Goals	Stage 1 Objectives		Stage 1 Measures
		Eligible Professionals	**Hospitals**	
		Record demographics o preferred language o insurance type o gender o race o ethnicity o date of birth	Record demographics o preferred language o insurance type o gender o race o ethnicity o date of birth o date and cause of death in the event of mortality	At least 80% of all unique patients seen by the EP or admitted to the eligible hospital have demographics recorded as structured data
		Record and chart changes in vital signs: o height o weight o blood pressure o Calculate and display: BMI o Plot and display growth charts for children 2-20 years, including BMI.	Record and chart changes in vital signs: o height o weight o blood pressure o Calculate and display: BMI o Plot and display growth charts for children 2-20 years, including BMI.	For at least 80% of all unique patients age 2 and over seen by the EP or admitted to eligible hospital, record blood pressure and BMI; additionally plot growth chart for children age 2-20
		Record smoking status for patients 13 years old or older	Record smoking status for patients 13 years old or older	At least 80% of all unique patients 13 years old or older seen by the EP or admitted to the eligible hospital have "smoking status" recorded
		Incorporate clinical lab-test results into EHR as structured data	Incorporate clinical lab-test results into EHR as structured data	At least 50% of all clinical lab tests ordered whose results are in a positive/negative or numerical format are incorporated in certified EHR technology as structured data
		Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, and outreach	Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, and outreach	Generate at least one report listing patients of the EP or eligible hospital with a specific condition.

Health Outcomes Policy Priority	Care Goals	Stage 1 Objectives		Stage 1 Measures
		Eligible Professionals	Hospitals	
		Report ambulatory quality measures to CMS or the States	Report hospital quality measures to CMS or the States	For 2011, provide aggregate numerator and denominator through attestation as discussed in section II(A)(3) of this proposed rule For 2012, electronically submit the measures as discussed in section II(A)(3) of this proposed rule
		Send reminders to patients per patient preference for preventive/ follow up care		Reminder sent to at least 50% of all unique patients seen by the EP that are age 50 or over
		Implement 5 clinical decision support rules relevant to specialty or high clinical priority, including diagnostic test ordering, along with the ability to track compliance with those rules	Implement 5 clinical decision support rules related to a high priority hospital condition, including diagnostic test ordering, along with the ability to track compliance with those rules	Implement 5 clinical decision support rules relevant to the clinical quality metrics the EP/Eligible Hospital is responsible for as described further in section II(A)(3).
		Check insurance eligibility electronically from public and private payers	Check insurance eligibility electronically from public and private payers	Insurance eligibility checked electronically for at least 80% of all unique patients seen by the EP or admitted to the eligible hospital
		Submit claims electronically to public and private payers.	Submit claims electronically to public and private payers.	At least 80% of all claims filed electronically by the EP or the eligible hospital
Engage patients and families in their health care	Provide patients and families with timely access to data, knowledge, and tools to make informed decisions and to manage their health	Provide patients with an electronic copy of their health information (including diagnostic test results, problem list, medication lists, allergies), upon request	Provide patients with an electronic copy of their health information (including diagnostic test results, problem list, medication lists, allergies, discharge summary, procedures), upon request	At least 80% of all patients who request an electronic copy of their health information are provided it within 48 hours

Health Outcomes Policy Priority	Care Goals	Stage 1 Objectives		Stage 1 Measures
		Eligible Professionals	Hospitals	
			Provide patients with an electronic copy of their discharge instructions and procedures at time of discharge, upon request	At least 80% of all patients who are discharged from an eligible hospital and who request an electronic copy of their discharge instructions and procedures are provided it
		Provide patients with timely electronic access to their health information (including lab results, problem list, medication lists, allergies) within 96 hours of the information being available to the EP		At least 10% of all unique patients seen by the EP are provided timely electronic access to their health information
		Provide clinical summaries for patients for each office visit		Clinical summaries are provided for at least 80% of all office visits
Improve care coordination	Exchange meaningful clinical information among professional health care team	Capability to exchange key clinical information (for example, problem list, medication list, allergies, diagnostic test results), among providers of care and patient authorized entities electronically	Capability to exchange key clinical information (for example, discharge summary, procedures, problem list, medication list, allergies, diagnostic test results), among providers of care and patient authorized entities electronically	Performed at least one test of certified EHR technology's capacity to electronically exchange key clinical information
		Perform medication reconciliation at relevant encounters and each transition of care	Perform medication reconciliation at relevant encounters and each transition of care	Perform medication reconciliation for at least 80% of relevant encounters and transitions of care
		Provide summary care record for each transition of care and referral	Provide summary care record for each transition of care and referral	Provide summary of care record for at least 80% of transitions of care and referrals

Health Outcomes Policy Priority	Care Goals	Stage 1 Objectives		Stage 1 Measures
		Eligible Professionals	Hospitals	
Improve population and public health	Communicate with public health agencies	Capability to submit electronic data to immunization registries and actual submission where required and accepted	Capability to submit electronic data to immunization registries and actual submission where required and accepted	Performed at least one test of certified EHR technology's capacity to submit electronic data to immunization registries
			Capability to provide electronic submission of reportable lab results (as required by state or local law) to public health agencies and actual submission where it can be received	Performed at least one test of the EHR system's capacity to provide electronic submission of reportable lab results to public health agencies (unless none of the public health agencies to which eligible hospital submits such information have the capacity to receive the information electronically)
		Capability to provide electronic syndromic surveillance data to public health agencies and actual transmission according to applicable law and practice	Capability to provide electronic syndromic surveillance data to public health agencies and actual transmission according to applicable law and practice	Performed at least one test of certified EHR technology's capacity to provide electronic syndromic surveillance data to public health agencies (unless none of the public health agencies to which an EP or eligible hospital submits such information have the capacity to receive the information electronically)

Health Outcomes Policy Priority	Care Goals	Stage 1 Objectives		Stage 1 Measures
		Eligible Professionals	Hospitals	
Ensure adequate privacy and security protections for personal health information	Ensure privacy and security protections for confidential information through operating policies, procedures, and technologies and compliance with applicable law. Provide transparency of data sharing to patient.	Protect electronic health information created or maintained by the certified EHR technology through the implementation of appropriate technical capabilities	Protect electronic health information created or maintained by the certified EHR technology through the implementation of appropriate technical capabilities	Conduct or review a security risk analysis per 45 CFR 164.308 (a)(1) and implement security updates as necessary

e. **Request for Public Comment on Potential Health It Functionality Measures for EPs and Eligible Hospitals in 2013 Payment Year and Subsequent Years (p 108):** CMS notes limitations on infrastructure necessary to support electronic exchange of structure information and therefore has set requirements lower than expected. This affects laboratory orders as well as the transmission of orders from the definition of CPOE use. CMS notes, however, that in future rulemaking to cover Stage 2 and Stage 3 that it anticipates raising the threshold for these objectives and covers its rational on page 109.

3. **Reporting on Clinical Quality Measures Using EHRs by EPs and Eligible Hospitals (p 110)**: This extensive section relates to reporting on clinical quality measures and reflects one of the three goals established through ARRA/HITECH to achieve meaningful use. It bears careful reading.

   CMS notes that HHS does not have the capacity to electronically accept data on clinical quality measures and will also have to promulgate technical specification for EHR vendors for such transmission. Therefore, for 2011 CMS is proposing that EPs and eligible hospitals **use an attestation methodology to submit summary information to CMS on clinical quality measures** as a condition of demonstrating meaningful use of certified EHR technology. A similar proposal is made for Medicaid. CMS does believe it will be ready to implement electronic submission by 2012, and if so, it will publish a notice.

   CMS defines "clinical quality measures" to consist of "measures of processes, experience, and/or outcomes of patient care, observations or treatment that relate to one or more quality aims for healthcare such as effective, safe, efficient, patient-centered, equitable, and timely care." CMS also proposes that the clinical quality measure adopted for Medicare also be used for Medicaid. While not requiring electronic reporting at this time, CMS is proposing that eligible providers "use certified EHR technology to capture the data elements and calculate the results for the applicable clinical quality measures" required and attest to this use. States have significant leeway here.

CMS discusses the variety of proposed clinical quality measures required of EPs. An extensive table (Table 3) is provided on pages 123-138, comprised primarily of Physician Quality Reporting Imitative (PQRI) and National Quality Forum (NQF) endorsed measures. CMS requests (p 139) for comments on both the clinical utility of the requirements as well as the state or readiness for use in the EHR incentive programs.

The NPRM covers some clinical quality measures reporting criteria for EPs and highlights two measure groups (p 141). There are some options in the requirements discussed and the specific requirements for various clinical groups are highlighted in tables from page 143 through 151. Quality measures for eligible hospitals are then addressed beginning on page 152 and extending through page 162. Again CMS is seeking comments on these measures and on proposed measures for 2013 (pp 162-163).

CMS lists its proposed reporting method for clinical quality measures for 2011 and 2012 payment years (beginning on page 163) with a series of attestations for 2011 (pp 164-166). In 2012, HHS expects to be ready to receive electronic reporting, with the technology requirements forthcoming. CMS notes that reporting does not have to be limited to Medicare and Medicaid patients and suggests that all cases to "which a clinical quality measure applies" be collected "in order to accurately assess the quality of care rendered by the particular EP or eligible hospital generally." Comments are solicited on this approach. CMS further notes its desire to eliminate duplicative or redundant reporting among programs under Medicare.

Further discussion in this section covers alternative reporting methods for clinical quality measures, proposed reporting criteria for EPs and eligible hospitals, and how dual eligibles will be addressed under this program.

4. **Demonstration of Meaningful Use (p 171):** This section echoes that on quality. CMS suggests that there be a common method of demonstration between Medicare and Medicaid and among the providers involved. CMS proposes an attestation method for demonstration in CY 2011and FY 2011 that would use some type of online portal since other methods may not yet be available. CMS also suggests that it work with the states to test further methods for the out years of the program. Any testing "should be based on the principal of electronic exchange of information from certified EHR technology." CMA plans to issue further instructions on the specifics for submitting attestation through "established outreach venues."

5. **Data collection for Online Posting Program coordination and Accurate Payments (p 174):** CMS first indicates the need to post on-line all participants in the incentive program. Then the section discusses the need to coordinate between the Medicare programs and Medicaid in order to insure there is not inappropriate duplication. This discussion also raises a one-time opportunity for EPs to switch from the Medicaid program to Medicare. CMS provides some examples of why this might be considered by an EP. The last year such an election can take place is 2014. Finally, CMS lists the data to be collected under this section.

6. **Hospital-based Eligible Professionals (p 179):** This section discusses hospital-based EPs that perform more than 90 percent of their covered professional services in a hospital setting. CMS notes that while the meaningful use criteria in Stage 1 for hospitals do not include outpatient clinics in its calculations, it is using services provided in these clinics when determining the

eligibility of the professional. CMS discusses how the Medicare and Medicaid programs will make such a determination through examination of previous claims. CMS takes this approach under the assumption that hospital-based professionals make use of hospital EHR systems.

CMS is concerned that the approach it is taking regarding meaningful use and outpatient primary care sites will result in a lag of EHR systems being applied to such settings. Comments are requested on all of the issues raised in this section both as to hospital and professional eligibility, including comments on whether CMS should use another method for defining hospital-based EPs rather than the one recommended here.

7. **Interaction with other Programs (p 189):** CMS notes that EP or group practice could be eligible for both the HITECH incentive as well as the current MIPPA E-prescribing Incentive Program. Those who accept the HITECH incentive will not receive the E-Prescribing payment in the same year.

B. Medicare Fee-for-Service Incentives (p 191)

1. **Incentive Payments for Eligible Professionals (p 191):** This section covers changes that have to be made with regard to physician payment under Medicare and provides a new definition of "eligible professional" to the Medicare regulations. This section also covers the incentive payment limits for EP and provides a number of examples covering different scenarios.

2. **Incentive Payments for Hospitals (p 205):** This section also provides a new definition for "hospital" under the Medicare program and covers the incentive payment calculations for hospitals, based on discharges, under the HITECH incentive programs. A number of examples and tables are provided covering the converging reimbursement rules and different scenarios.

3. **Incentive Payments for Critical Access Hospitals (p 224):** This section duplicates those immediately above with regard to definitions, calculations, and limits for CAHs.

4. **Process for Making Incentive Payments under the Medicare FFS Programs (p 235):** Finally CMS covers how incentive payments will be made to eligible entities.

C. Medicare Advantage Organization Incentive Payments (p 240):

This is an extensive section covering Medicare Advantage (MA) programs and their eligibility for incentives under HITECH. Complicating this discussion even further, CMS deliberates how a MA program might have with EPs or eligible hospitals. Given that this is a small segment of the eligible population, we will not provide an overview beyond identifying the different subsections; however, anyone associated with a MA program should pay close attention to this section especially since MA could have an early reporting requirement under the proposed rule. As with all sections, CMS welcomes comments. The subsections include:

1. Definitions (p 240)
2. Identification of Qualifying MA Organizations, MA EPs, and MA-Affiliated Eligible Hospitals (p 248)
3. Computation of Incentives to Qualifying MA Organizations for MA, EPs and Hospitals (p 251)
4. Timeframe for Payment (p 263)

5. Avoiding Duplicate Payment (p 265)
6. Meaningful User Attestation (p 268)
7. Posting on Website and Limitation on Review (p 270)
8. Limitation on Review (p 271)
9. Conforming Changes (p 272)
10. Payment Adjustment and Future Rulemaking (p 273)

D. Medicaid Incentives (p 275)

1. **Overview of Health Information Technology in Medicaid (p 275):** CMS provides an overview of how the HITECH Act components fit with other programs associated with Medicaid as well as grants and other funding provided to Medicaid programs from HHS. CMS also notes that states have a significant opportunity to build upon prior and current efforts in order to achieve interoperable health information exchange.

2. **General Medicaid Provisions (p 279):** This is a short section that indicates that States, at their option, may receive: (1) 90 percent payment from CMS for State expenditure related to the administration of an EHR incentive program for certain Medicaid providers that are adopting, implementing, or upgrading and meaningfully using certified EHR technology; and (2) 100 percent payment FFP for State expenditures for those incentive payments.

3. **Identification of Qualifying Medicaid EPs and Eligible Hospitals (p 279):** Similar to previous sections, this section covers who is eligible for incentive payments under Medicaid, including physicians, dentists, certified nurse-midwives, nurse practitioners, and physician assistants practicing in a Federally Qualified Health Center (FQHC) or a Rural Health Center (RHC). Like Medicare, EPs cannot be "hospital-based" using the same definitions as those proposed for Medicare with the exception of FQHCs or RHCs. There are volume requirements proposed for EPs under the Medicaid program.

   Hospitals are limited to acute care facilities which CMS defined as having an average patient's length of stay not exceeding 25 days. This limits long term care facilities, which CMS suggests is the intent of the HITECH Act. "Children's Hospitals" also qualify under Medicaid and the NPRM proposes the requirements for children's hospitals that would not include hospitals with a pediatric wing or a hospital within a hospital.

   This section also defines "entities promoting the adoption of certified EHR technology and provides a means of payment to such entities [including health information exchanges (HIEs)] under the incentive program.

4. **Computation of Amount Payable to Qualifying Medicaid EPs and Eligible Hospitals (p 293):** This section covers the payment methodology proposed for Medicaid and how it was arrived at. CMS provides a number of tables and scenarios to describe just how it proposes payment over the course of the HITECH stages. The section also covers a category of early adopters and how states should track reports and other required activities of providers.

   It should be noted (p 320) that CMS proposes that for EPs and hospitals with multi-state Medicaid practice locations, the provider may annually pick only one state from which to receive incentive payments. "In other words, a provider would not be able to receive incentive

payments from more than one state in the same year." CMS suggests it would be too complex for state agencies as well as CMS. CMS suggests that states consider "these border state providers when developing their policies and attestation methodology."

5. **National Level Repository and State Data Collection (p 321):** CMS suggests that a single provider election repository be developed (See above II.A.5) to "collect a minimum amount of information on all EPs and hospitals to prevent duplicative payment and coordinate technical assistance."

6. **Collection of Information Related to the Eligible Professional's National Provider Identifier and the Tax Identification Number (TIN) (p 322):** Similar to EPs and hospitals choosing one state, CMS also proposes that EPs in multiple group practices or multiple types of practice locations select one TIN for payment.

7. **Activities Required to Receive Incentive Payments (p 322):** This section provides a general overview of what EPs and hospitals must do to qualify – "engage in efforts to adopt, implement, or upgrade certified EHR technology." Over the years of participation they must demonstrate meaningful use in a manner approved by the state and the Secretary.

   Unlike the Medicare incentive programs, the Medicaid program allows eligible providers to receive an incentive payment even before they have begun to meaningfully use certified EHR technology. CMS defines adopting, implementing, or upgrading certified EHR technology as "the process by which providers have installed and commenced utilization of certified EHR technology capable of meeting meaningful use requirements; or expanded the available functionality and commenced utilization of certified EHR technology capable of meeting meaningful use requirements at the practice site, including staffing, maintenance, and training." CMS proceeds to discuss this concept further (p 324) and how states might establish this process.

   States will be subject to the same rolling stages and would be required to validate that incentive recipients have met all of the eligibility criteria to qualify for payment. CMS seeks comments on the validation process. CMS also discusses the ability of states under HITECH to add to the requirements for meaningful use and how Medicaid Transformation Grants might be used.

   CMS also suggests that clinical quality measures be considered as proposed above and further notes that the definition of meaningful use will change over time.

8. **Overview of Conditions for States to Receive FFP for Incentive Payments and Implementation Funding (p 333):** This section covers the requirements states must meet and how they can receive federal financial participation reimbursement.

9. **Financial Oversight, Program Integrity and Provider Appeals (p 344):** this section specifies what financial oversight must be provided by states and what the federal government will be doing to monitor state programs and the use of ARRA funds.

III. Collection of Information Requirements (p 347)

This section outlines requirements for the various reporting by providers and states that must occur under this incentive program. There is an extensive description of what information must be collected and when, as well as estimates of the time that it will take to complete the supplying of information. Listed below are the sections for this requirement as required of CMS by the Paperwork Reduction Act of 1995:

A. Demonstration of Meaningful Use Criteria (p 348)

B. Participation Requirements for EPs, Eligible Hospitals, and Qualifying CAHs (p 372)

C. Identification of Qualifying MA Organizations, MA-EPs and MA-affiliated Eligible Hospitals (p 379)

D. Incentive Payments to Qualifying MA Organizations for MA-EPs and Hospitals (p 382)

E. Meaningful User Attestation (p 384)

F. Incentive payments to qualifying MA organizations for MA-eligible Professionals and Hospitals (p 386)

G. Process for Payments (p 387)

H. Activities Required to Receive an Incentive Payment (p 388)

I. State Monitoring and Reporting Regarding Activities Required to Receive an Incentive Payment (p 389)

J. State Responsibilities for Receiving FFP (p 390)

K. Prior Approval Conditions (p 390)

L. Termination of Federal Financial participation (FFP) for Failure to Provide Access to Information (p 391)

M. State Medicaid Agency and Medicaid EP and Hospital Activities (p 392)

N. Access to Systems and Records (p 392)

O. Procurement Standards (p 393)

P. State Medicaid Agency Attestations (p 395)

Q. Reporting Requirements (p 396)

R. Retroactive Approval of FFP with an Effective Date of February 18, 2009 (p 397)

S. Financial Oversight and monitoring Expenditures (p 397)

T. Appeals Process for a Medicaid Provider Receiving EHR Incentive Payments (p 399)

IV. Response to Comments (p 404)

This section notes that CMS cannot respond individually to any comments received; however, all comments received within the due dates (to be published) will be considered.

V. Regulatory Impact Analysis (p 404)

All NPRMs are required to have a regulatory impact analysis which is designed to indicate the positive and negative impact or burdens anticipated from the regulation on those regulated.

A. Overall Impact (p 404):

CMS suggests that the impacts of this regulation are very uncertain since the NPRM is one of three being proposed and the rule itself can change due to the comments received. CMS further notes that there are a number of variables depending on the EHR readiness of providers, the variability in when a provider might enter the program, if at all, and under which program it might receive payment(s).

B. Regulatory Flexibility Analysis (p 410):

CMS has always defined healthcare entities as essentially small entities. While pointing to the variability just noted, CMS also notes that most EPs using EHR systems will require significant change to achieve certification or achieve meaningful use. Other requirements will again vary. CMS also notes that it has limited flexibility in implementing the provision of ARRA/HITECH and the only leeway was in the requirements for meaningful use and measures which it tried to balance in order to achieve the goals of the legislation. Some alternatives related to the reporting of quality measures are covered. CMS in summary notes that while the program is economically significant it does not believe that the net effect on individual providers will be negative over time except in rare cases.

C. Small Rural Hospitals (p 414):

Similarly, CMS notes that the proposed rule would affect the operations of a substantial number of small rural hospitals because they are required to adopt certified EHR technology by 2015 or face adjusted payments. Again, CMS suggests in the long run the impact on rural eligible hospitals would be positive.

D. Unfunded Mandates Reform Act (p 415):

CMS suggests that the NPRM does not constitute an unfunded mandate as defined by law and notes that the states' role is to essentially manage the program for which it will be funded.

E. Federalism (p 416):

Similarly, CMS suggests that there is nothing in the NPRM that impacts the states significantly.

F. Anticipated Effects (p 417):

CMS notes that it is providing assumptions and potential costs for industry's implementation of HIT as referenced in the next section.

G. HITECH Impact Analysis (p 417):

This section covers the need for the regulation – to implement ARRA – and the alternatives possible, which CMS previously noted were limited due to the detail of the legislation. CMS lists its assumptions as to the number of entities (EPs, hospitals, and other that might be covered by the rule).

CMS suggests that the average adopt/implement/upgrade cost for EPs is $54,000 per physician FTE, while annual maintenance costs will average $10,000 per physician FTE. The range for eligible hospitals is $1 million to $100 million averaged to $5 million for installation. CMS seeks further information on these costs and the costs for "certified EHRs." Additional detail is provided (beginning on page 422) for EPs and hospitals. CMS notes that it did not include estimates on Federal hospitals.

CMS also provides an estimate of the incentives to be paid out and the numbers of EPs and hospitals to whom payments will be made. The overall costs and benefits are reviewed over a 10 year basis and there is significant variation in numbers.

H. Accounting Statement (p 450):

This is a Pro Forma statement

Proposed Rule (p 452):

This is where the actual rule and language begin. The final wording will be directly impacted by the comments made to this proposed rule.