

**CHIME Summary - HITECH ACT**  
**CMS Proposed Rules**  
**ONC Interim Final Rules**  
**January 5, 2010**

On December 30, 2009, the Department of Health and Human Services (HHS) released two widely anticipated regulations needed to implement the health information technology (IT) provisions of the American Recovery and Reinvestment Act of 2009 (ARRA).

The Centers for Medicare and Medicaid Services released a proposed rule to guide implementation of an electronic health records (EHR) incentive program under Medicare and Medicaid. CMS will accept public comment on its proposal through March 1, 2010. The rule, entitled Electronic Health Record (EHR) Incentive Program (CMS-0033-P), is available at: [http://www.federalregister.gov/OFRUpload/OFRData/2009-31217\\_PL.pdf](http://www.federalregister.gov/OFRUpload/OFRData/2009-31217_PL.pdf)

The Office of the National Coordinator for Health Information Technology (ONC) issued an interim final rule that lays out technical health IT standards and certification requirements that will be adopted by the federal government. The interim final rule becomes effective 30 days after publication; however, ONC will accept public comments for 60 days. The rule, entitled Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Health Information, is available at: [http://www.federalregister.gov/OFRUpload/OFRData/2009-31216\\_PL.pdf](http://www.federalregister.gov/OFRUpload/OFRData/2009-31216_PL.pdf)

The federal government has yet to release a third regulation that lays out the process for product certification. ONC will likely release that rule in early 2010.

This document provides a high-level summary of both regulations, with a stronger emphasis on the CMS regulation governing the EHR Incentive Program.

## **EHR Incentive Program (CMS)**

The proposed rule from CMS provides a complex array of definitions, objectives, measures, and reporting requirements for physicians and hospitals seeking to qualify for the EHR incentive payments.

Overall, CMS estimates that only \$14 to \$28 billion will be paid out in EHR incentive payments over ten years. This estimate is much lower than the previous federal estimates of about \$34 billion.

Selected aspects of the proposed rule are highlighted below:

**Phased Approach:** CMS proposes to define meaningful use of EHRs through three phases, with more stringent criteria applied in each phase:

- **Stage 1 (2011 and 2012)** focuses on electronically capturing health information in a coded format, using that information to track key clinical conditions, communicating that information for care coordination purposes, implementing some clinical decision support tools, and initiating the reporting of clinical quality measures and public health

information.

- **Stage 2 (2013 and 2014)** will expand on the earlier measures to focus on continuous quality improvement at the point of care and the exchange of information in the most structured format possible.
- **Stage 3 (2015 and beyond)** will focus on promoting improvements in quality, safety and efficiency, focusing on decision support, patient access to self-management tools, access to comprehensive patient data, and improving population health.

CMS proposed specific objectives and measures for Stage 1 in the rule. Requirements for the later stages will be laid out in future rulemaking.

**Transition:** The proposed rule adopts a modification of the “adoption year approach” recommended by the HIT Policy Committee. To provide some transition time, CMS proposes applying the Stage 1 criteria to all hospitals in their first year of meaningful use incentive payments, as long as they become eligible before 2015. Later adopters, however, would need to meet the Stage 2 and Stage 3 criteria on the same schedule as early adopters. For example, a hospital that first received an EHR incentive payment in FY 2013 would need to meet only the Stage 1 criteria in that year, but in FY 2014, it would need to meet the Stage 2 criteria. In 2015, all hospitals and eligible providers would need to meet the Stage 3 criteria to avoid the payment penalties. CMS provides the following chart on which objectives providers must meet in their first year of first eligibility:

**Stage of Meaningful Use Criteria by Payment Year**

First Payment Year	Payment Year				
	2011	2012	2013	2014	2015 and beyond
2011	Stage 1	Stage 1	Stage 2	Stage 2	Stage 3
2012		Stage 1	Stage 2	Stage 2	Stage 3
2013			Stage 1	Stage 2	Stage 3
2014				Stage 1	Stage 3
2015 and beyond					Stage 3

**Objectives and Measures of HIT Functionality:** To qualify for the incentive payments in both Medicare and Medicaid, eligible providers and hospitals must use certified EHRs to meet specific objectives and report specific HIT functionality measures to CMS. CMS proposed 23 objectives and related measures for hospitals and 25 objectives and related measures for eligible providers for Stage 1 (2011 and 2012). Many, but not all, of the objectives and measures are the

same for both provider groups. Additional quality measures will also need to be submitted and are described below.

The proposed objectives are closely aligned with the recommendations of the HIT Policy Committee. The specific measures, however, are more numerous and specific than the HIT Policy Committee recommendations and will likely be burdensome to report. Many of the measures include denominators that span electronic and paper-based systems (such as percent of all orders entered through CPOE).

CMS summarizes the 2011/2012 objectives and measures in Table 2 of the proposed rule (Attachment I). The text of the rule provides more detailed definitions, including numerators and denominators, for these measures. (For your convenience, Attachment II – HIT Functionality Measures provides the CMS definitions in tabular form.)

It should be noted that for hospitals, these proposed definitions are generally restricted to services provided in the inpatient environment, as defined by CMS Place of Service Code 21 (the POS is included on claims.). Thus, EHR systems used in emergency departments (POS = 23), ambulatory clinics (POS = 22), and ambulatory surgery (POS = 24) centers would not contribute to the calculation of the measures (including the share of orders placed through CPOE). For example, emergency department orders entered through CPOE would not count toward the 10 percent requirement. In addition, many of the measures require hospitals and eligible providers to count unique patients.

Selected objectives of particular note for hospital and health system CIOs are listed below; where a specific threshold must be met, it is noted.

- Use CPOE for orders (any type) directly entered by the authorizing provider (at least 10 percent in eligible hospitals, and at least 80 percent in the physician office)
  - CPOE is defined as: “entailing the provider’s use of computer assistance to directly enter medial orders (for example, medications, consultations with other providers, laboratory services, imaging studies, and other auxiliary services) from a computer or mobile device. The order is also documented or captured in a digital, structured, and computable format for use in improving safety and organizations.”
  - For 2011 and 2012, electronic transmission of the order to a pharmacy, lab, or other party is not required.
- Incorporate all clinical lab test results into the EHR as structured data (at least 50 percent)
- Implement five 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

- Check insurance eligibility electronically from public and private payers (at least 80 percent of unique patients admitted to the hospital)
- Provide patients who request it with an electronic copy of their health information (including diagnostic test results, problem list, medication lists, allergies, discharge summary, procedures) within 48 hours (at least 80 percent)
- Provide patients with an electronic copy of their discharge instructions and procedures at time of discharge, upon request (80 percent of those making a request)
- Perform medication reconciliation at each transition of care (80 percent of transitions)

CMS did NOT include some of the objectives recommended by the HIT Policy Committee, such as recording advanced directives, providing access to patient-specific educational resources, and requiring physicians to document progress notes in the EHR. In addition, CMS either did not include recommended objectives that require electronic exchange of information or set a low bar for objectives that involve exchange. For example, hospitals will only need to demonstrate that they have 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).

**Reporting requirements:** To receive the incentive payments, providers will need to:

- Use certified EHRs;
- Demonstrate meaningful use by providing data on the measures of HIT functionality; and
- Report quality measures using data generated from their EHRs.

CMS proposes that providers meet meaningful use requirements primarily through attestation. Hospitals and eligible providers will be expected to:

- Attest that they used certified EHR technology (as defined in the ONC rule and discussed below);
- Specify the technology used;
- Attest that they have satisfied each of the applicable objectives; and
- Provide data on each of the HIT functionality measures.

**Quality Reporting:** Providers will also be expected to submit data on new clinical quality measures included in the proposed rule:

- CMS proposes that physicians report on a combination of four core measures and a set of measures specific to individual specialties. Many, but not all, of the physician measures are currently part of the Physician Quality Reporting Initiative. In all, 90 physician measures are included in the proposed rule (Table 3 in the proposed rule).
- CMS proposes that hospitals report on 35 quality measures, of which only nine are

currently in use in the Medicare pay-for-reporting program.

In recognition of its limited ability to receive quality data electronically, CMS proposes that in 2011, hospitals use attestation to submit summary information on each quality measure (numerator, denominator, and exclusions). (See Attachment III – AHA Chart of Inpatient Quality Measures). However, CMS proposes to require that hospitals generate the data and calculate the results for quality measures using their certified EHR technology. Beginning in 2012, CMS proposes electronic submission of quality measures.

**Reporting Period:** In general, CMS expects the reporting period to cover all of a calendar year for physicians and a fiscal year for hospitals. However, to provide more time for initial implementation, CMS proposes that in FY/CY 2011, the reporting period be shortened to include any continuous 90-day period that falls within the fiscal (hospital) or calendar (eligible provider) year.

**Eligible Providers:** CMS proposes strict definitions for eligible providers and hospitals that will limit the number of providers eligible to receive payments.

- **Hospitals:** Subsection (d) (PPS hospitals) and Critical Access Hospitals (CAHs) are subject to the EHR incentive program and penalties. CMS proposes to identify a hospital by using its Medicare provider number (referred to as the CMS Certification Number, or CCN, in the rule). Multiple hospitals campuses sharing one CCN will receive only one incentive payment.
- **Hospital-based Professionals:** By law, hospital-based physicians are not eligible for incentive payments and are not subject to Medicare penalties. CMS proposes to define a physician with 90 percent or more of his/her services provided in an inpatient hospital, outpatient hospital, or emergency department setting as hospital-based. CMS estimates that about 30 percent of physicians are hospital-based.

**Interaction with Medicaid:** In their first year of eligibility for Medicaid incentives, providers do not have to meet the meaningful use criteria – they can qualify by adopting, implementing, or upgrading to certified EHR technology. In later years, however, hospitals and eligible physicians must demonstrate meaningful use of EHRs to the states in order to receive Medicaid incentive payments.

To align the two programs, CMS proposes using similar meaningful use definitions across Medicare and Medicaid. The agency proposes that states use the Medicare meaningful use definition, including objectives and measures, as a “minimum standard” for their Medicaid programs. CMS proposes to allow states to add additional objectives to the definition or modify existing objectives only if those changes “further promote the use of EHRs and healthcare quality” and do not “require additional functionality beyond that of certified EHR technology.”

CMS also proposes to deem any hospital that is a meaningful EHR user under Medicare also to be classified as a meaningful user for Medicaid, as hospitals can receive payments in both programs. Eligible providers, however, must choose between the two incentive programs in their first payment year. CMS proposes that they be allowed to switch between Medicare and Medicaid one time before 2014.

Eligible providers and hospitals may only receive Medicaid incentive payments from one state, even if they are licensed to practice in multiple states. As with Medicare, the rule proposes to define a hospital by its CCN. Hospital-based eligible providers cannot receive Medicaid incentive payments.

In general, CMS proposes that the clinical quality measures adopted for the Medicare EHR incentive program will also apply to the Medicaid EHR incentive program. However, the agency provides an alternative list of Medicaid-specific pediatric quality measures for use by providers seeing eligibility under the Medicaid program.

The rule also provides direction to the states on their Medicaid EHR incentive programs, which are OPTIONAL for the states.

CMS proposes that, in general, the Medicaid incentive programs begin in 2011.

The states must provide CMS with several documents before they can receive federal matching funds (90 percent) to cover the costs of administering the state-level Medicaid EHR incentive program and making incentive payments (Federal match is 100 percent for incentives).

States must submit a Health Information Technology Implementation Advance Planning Document (HIT-APD) as well as a State Medicaid Health Information Technology Plan (SMHP). CMS reports that, to date, 13 states have had their documents approved and received funding. The proposed rule also places contracting, reporting, and fraud and abuse control requirements on states that want to receive federal matching funds.

The Medicaid program includes patient volume thresholds for eligibility. The proposed rule establishes the process for determining eligibility, although a state may request permission from CMS to set a different process. CMS proposes that providers attest to their Medicaid volume based on the share of encounters that are covered by Medicaid (fee-for-service and managed care) “over any continuous 90-day period in the most recent calendar year”. The thresholds are:

- 10 percent for acute care hospitals (no threshold for children’s hospitals)
- 30 percent for eligible providers (20 percent for pediatricians)
- For eligible providers practicing predominantly in a Federally Qualified Health Center (FQHC) or Rural Health Clinic (RHC), the threshold is defined as 30 percent of patient volume attributable to needy individuals, which includes Medicaid, SCHIP, uncompensated care, and those furnished services at either no cost or reduced cost based on ability to pay. In this case, “predominantly” is defined as more than 50 percent of

total patient encounters over a period of 6 months in the most recent calendar year.

**Privacy:** In the proposed rule, CMS states that compliance with the HIPAA privacy and security rules is required for all covered entities, regardless of their participation in the EHR incentive program. Therefore, the agency proposes that “meaningful use of certified EHR technology supports compliance with HIPAA and the fair data sharing practices outlined in the Nationwide Privacy and Security Framework.” The proposed rule does not include additional regulatory requirements beyond those in the HIPAA Privacy and Security Rules. It does, however, require providers to conduct or review a security risk analysis according to the HIPAA regulations and implement security updates as necessary.

**Payment:** Hospitals will receive interim payments from Medicare, with final payment calculated and distributed upon settlement of the cost report. This process is similar to other payment adjustments in the IPPS, such as the indirect medical education adjustment. Payments for eligible providers will be based on the individual taxpayer identification number and be the lower of 75 percent of allowed Medicare charges in the payment year or the set limits established in ARRA (a total of \$44,000 over five years for most physicians). Payments will not be made by group practice; however, eligible providers can reassign their incentive payments to their employer or to an entity with which they have a contractual arrangement (as they can do for all Medicare payments). The states will establish payment mechanisms for the Medicaid program.

## **Standards, Implementation Specifications, and Certification Requirements (ONC)**

The interim final rule from ONC provides a definition of certified EHRs and an initial set of standards, implementation specifications, and certification criteria for EHRs. The rule draws on recommendations from the HIT Standards Committee, as well as previous federal efforts to recognize specific standards. According to ONC, the certification criteria adopted in the IFR “specify the capabilities and related standards that certified EHR technology must include in order to support the proposed meaningful use Stage 1 meaningful requirements” laid out by CMS.

**Certification Criteria:** ONC organizes the certification criteria according to each of the Stage 1 meaningful use requirements and summarizes them in Table 1 of the rule (Attachment IV). The certification criteria apply to EHR products, not providers. Separate descriptions are provided for hospitals and physicians, where needed.

**Demonstrating Use of A Certified Product:** Together, the CMS and ONC rules place a significant burden on providers to demonstrate that they are using “certified EHR technology.”

To receive the Medicare and Medicaid incentive payments, providers must attest to CMS that the EHR system they use meets the statutory definition of a qualified EHR and has been “tested and certified in accordance with the certification program established by the National Coordinator.” The actual certification process will be described in a forthcoming proposed rule from ONC.

In the IFR, ONC lays out a multi-stage definition of “certified EHR technology.” Providers may choose to use either a “complete EHR,” which has been developed to meet all of the applicable certification criteria adopted by the HHS Secretary, or a combination of EHR modules, which can be “any service, component, or combination thereof that can meet the requirements of at least one” of the certification criteria adopted by the Secretary.

ONC states that providers who choose to combine multiple EHR modules are responsible for ensuring that the modules work together and that, together, they meet all of the certification criteria.

Neither the CMS nor the ONC rule provides for acceptance of previous CCHIT certification or allows for a transition time between when certification criteria are announced and when providers will be expected to use products certified to those criteria.

**Standards:** The IFR also adopts an initial set of standards and implementation specifications organized into four categories:

- Vocabulary standards –Nomenclatures and code sets used to describe clinical problems and procedures, medications, and allergies;
- Content Exchange – Standards used to share clinical information such as clinical summaries, prescriptions, and structured electronic documents;
- Transport – Standards used to establish a common, predictable, secure communication protocol between systems; and
- Privacy and Security – Standards (e.g., authentication, access control, transmission security) which relate to and span across all of the other types of standards.

The rule lays out specific standards to support Stage 1 of meaningful use, but also identifies likely future candidates to support Stage 2. To be certified, EHR technology must support use of these standards. For the time being, however, few of the meaningful use requirements that apply to providers specify use of the standards in implementation.

The IFR also provides detailed standards to support the privacy and security of health information. According to ONC, however, the interim final rule “strictly focuses on the capabilities of Certified EHR Technology and does not change existing HIPAA Privacy Rule or Security Rule requirements.” In addition, ONC specifically states that meeting these certification requirements does not guarantee compliance with the HIPAA Privacy or Security Rules. In the future, however, ONC and the HIT Policy and Standards Committees expect to “look at capabilities beyond those explicitly specified in the HIPAA Security Rule.”

The specific standards adopted by category are:

- Transport
  - Simple Object Access Protocol (SOAP) version 1.2
  - Representational state transfer (REST)
- Content Exchange and Vocabulary
  - As laid out in Table 2A from the ONC proposed rule (Attachment V)
- Privacy
  - As laid out in Table 2B from the ONC proposed rule (Attachment VI)