

***What You Need to Know Now about the
Meaningful Use Proposed Rule
AND
Standards, Implementation Specifications, and
Certification Criteria Interim Final Rule***

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January 21, 2010

Two Proposed Rules

- Meaningful Use – Medicare and Medicaid EHR Incentive Programs
- Standards, Implementation Specifications, and Certification Criteria

Five Broad Healthcare Goals for “Meaningful Use”

1. Improve quality, safety, efficiency, and reduce health disparities
2. Engage Patients and Families
3. Improve Care Coordination
4. Ensure adequate privacy and security protections for Personal Health Info
5. Improve Population and Public Health

Considerations for Defining Meaningful Use

- Balance competing considerations of proposing a definition that best ensures reform of healthcare and improved healthcare quality
- Encourage widespread EHR adoption
- Avoid imposing excessive or unnecessary burdens on healthcare providers, while simultaneously acknowledging the short time-frame available
- Promote innovation

Meaningful Use Defined

- An EP and an eligible hospital shall be considered a meaningful EHR user for an EHR reporting period for a payment year if they meet the following three requirements:
 - Use certified EHR in a meaningful manner (ex. E-Prescribing)
 - Utilize certified EHR technology that is connected in a manner that provides for the electronic exchange of health information to improve the quality of healthcare such as promoting care coordination
 - Submit information on clinical quality measures and other measures in a form and manner specified by the Secretary

Meaningful Use – Medicare and Medicaid EHR Incentive Programs

Meaningful Use NPRM:

- Combined program: “The Medicare and Medicaid EHR Incentive Programs”
- Released as a Notice of Proposed Rule Making for public comment on December 30, 2009.
- 556-page document will be officially published in the Federal Register on January 13, 2010, and includes a 60-day comment period.
- A final rule is anticipated by late Spring

Key Definitions - Eligibility

- **Eligible Professional**

- **Medicare:** Doctor of Medicine, Doctor of Osteopathy, Dental surgeon, Doctor of Dental Medicine, Podiatrist, Optometrist, Chiropractor
- **Medicaid:** Physicians, Pediatricians, Dentists, Certified Nurse Midwives, Nurse Practitioners, Physicians Assistants operating at an FQHC/RHC led by a Physician Assistant

- **Eligible Hospital**

- **Medicare:** Subsection (d) hospitals that are paid under the hospital inpatient prospective payment system, Critical Access Hospitals; must reside in 50 the states or District of Columbia
- **Medicaid:** Acute Care Hospitals, Childrens' Hospitals

Key Definitions – Certified EHR

- A complete EHR or a combination of EHR modules, each of which:
 - meets the requirements of a Qualified EHR; and
 - has been tested and certified in accordance with the certification program established by the National Coordinator as having met all applicable certification criteria adopted by the Secretary.

Key Definitions – Payment Year

- **For a Medicare eligible professional**, a payment year is a calendar year starting in 2011.
- **For a Medicaid eligible professional**, a payment year begins in 2010 for adoption, implementation, or upgrading of a certified EHR. Meaningful use begins in 2011.
- **For an eligible hospital** or a critical access hospital, a payment year is the federal fiscal year (October 1 - September 30) starting in fiscal year 2011 (i.e. October 1, 2010)

Key Definitions – EHR Reporting Periods

- **For an eligible professional**
 - For the first payment year, any continuous 90-day period within a calendar year
 - For the second, third, and fourth payment year, the calendar year
- **For a eligible hospital or a critical access hospital**
 - For the first payment year, any continuous 90-day period within the Federal fiscal year
 - For the second, third, and fourth payment year, the Federal fiscal year

Medicare and Medicaid EHR Incentive Programs

Design -- Three-stage effort (pages 40-43 of the NPRM):

- **Stage I** – Electronic capture of health information in a coded format; tracking key clinical conditions and communicating outcomes for care coordinating; implementing clinical decision support tools to facilitate disease and medication management; and reporting outcomes for public health purposes.
- **Stage II** – Expands on stage I. Encourages the use of health IT to enhance computerized provider order entry; transitions in care; electronic transmission of diagnostic test results; and, research.
- **Stage III** – Expands on stage II. Promotes improvements to quality and safety; focuses on clinical decision support at a national level by encouraging patient access and involvement; and, improved population health data.

Incentive Programs Stage I Requirements

- Certified EHR technology that includes 25 measures; 17 measures require attestation by the provider; eight require information submitted by the provider.
- Requires Computerized Provider Order Entry (CPOE) for 10% of all hospital orders and 80% of all eligible providers' orders
- Delineates robust clinical quality measures for eligible professionals (EPs) and eligible hospitals.
- Requires patients be provided with an electronic copy of test results, problem lists, medication lists, and discharge summary upon request.

Incentive Programs Stage I Requirements

- Hospitals and EPs able to use an **attestation** methodology to submit summary information to CMS in 2011. Expect a formalized process from HHS by 2012.
- Hospitals eligible for Medicare and Medicaid incentives (volume threshold); EPs must choose between programs
- Hospitals and EPs must implement five clinical decision support rules relevant to clinical quality measures.

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.

Table 1 on Page 46 of the Medicare and Medicaid Programs; EHR Incentive Program (CMS-0033-P) December 2009

Eligible Professionals

- **Clinical Data Repository** – store, retrieve, and manage medications and laboratory and radiology results.
- **Clinical Documentation** – provide appropriate referrals, problem list, current medication list.
- **Clinical Decision Support** – implement drug-drug, drug-allergy, and drug-formulary checks.
- **CPOE** - in the areas of medications, laboratories, radiology/imaging, and provider referrals.
- **E-Prescribing** - Requires electronic generation and transmission of permissible prescriptions.

Eligible Hospitals

- **Clinical Data Repository** – store, retrieve, and manage laboratory and radiology results.
- **Clinical Documentation** – nursing and physician in the areas of discharge, transfer, care coordination, problem list, demographic capture, vital signs and BMI, smoking status (for patients 13 years and older); calculate and electronically display quality measure results.
- **Clinical Decision Support** – implement the five automated, clinical rules.
- **CPOE** – in the areas of medications, laboratories, radiology/imaging, blood bank, physical therapy, occupational therapy, respiratory therapy, rehabilitation therapy, dialysis, provider consults, and discharge/transfer.

Meaningful Use and Health Information Exchange

What We Know:

- The state of electronic exchange varies widely across the country and is dependent on numerous Federal, State, and local non-profit / for-profit initiatives.
- CMS will be issuing considerable updated guidance for participants to explore electronic exchange of information. A phased approach has been identified as the best approach. This will allow meaningful use criteria to be developed based on available technology capabilities.
- It is anticipated that the meaningful use criteria will be updated over time through future rulemaking.
- This current NPRM focuses on Stage 1. It is anticipated that the future Stage 2 and State 3 definitions will provide more clarity around health information exchange.
- In demonstrating meaningful use of certified EHR technology, exchange of information through an HIE/HIO is not required in Stage 1. Table 2 on page 103 provides an overview of the data exchange testing requirements.

Meaningful Use and Health Information Exchange

STAGE I

- In Stage 1 criteria, EPs and eligible hospitals must test their ability to send such information at least once prior to the end of the EHR reporting period. Testing should be performed by EPs and eligible hospitals on the exchange of clinical information, submission of electronic data to immunization registries, and electronic syndromic surveillance data to public health agencies.

Eligible hospitals should test capability to provide electronic submission of reportable lab results to public health authorities.

Meaningful Use and Health Information Exchange

Information Collection Options:

1. Require eligible participants to use the CMS-designated portal and submitting data based on specified structures such as CDA
2. Permit data measures through HIE/HIO. This method is dependent on the Secretary's ability to collect data through a HIE/HIO network and requires the participants to be a participating member of the HIE/HIO network.
3. Accept submission through registries dependent upon development of capacity and infrastructure.

Meaningful Use and Health Information Exchange

CMS intends to post the HIE/HIO participating member definition and other specifications for submission online.

The anticipated dates are

- On or before April 1, 2011 – Eligible hospitals
- On or before July 1, 2011 – Eligible professionals

Standards and Certification Criteria Interim Final Rule (IFR)

Standards and Certification Criteria IFR

- **Title:** “Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology”
- Released as an Interim Final Rule for public comment on December 30, 2009
- 136-page document will be officially published in the Federal Register on January 13, 2010, effective 30 days after publication
- Includes a 60-day comment period
- A final rule is expected in late spring 2010

Standards and Certification Criteria IFR

Relevant Themes

- Creates a floor for standards, implementation specifications, and certification criteria for meaningful use.
- Creates specific standards in 2011 in four areas:
 1. Vocabulary
 2. Content exchange
 3. Transporting of information
 4. Privacy and security

Standards and Certification Criteria IFR

Relationship to Meaningful Use

- The HITECH Act fundamentally ties the standards, implementation specifications, and certification criteria adopted in this IFR to the incentives available under the Medicare and Medicaid EHR Incentive Programs by requiring the meaningful use of Certified EHR Technology.
- Certification criteria described in the IFR establish the capabilities and standards that certified EHR technology will need to, at a minimum, support the achievement of proposed meaningful use Stage 1 by EPs and hospitals.

Key Definitions

- **Standard** - a technical, functional, or performance-based rule, condition, requirement, or specification that stipulates instructions, fields, codes, data, materials, characteristics, or actions.
- **Implementation Specification** - specific requirements or instructions for implementing a standard
- **Certification Criteria** -
 - 1) to establish that health IT meets applicable standards and implementation specifications adopted by the Secretary; or
 - 2) that are used to test and certify that health IT includes required capabilities.

Key Definitions – Qualified EHR

- “An electronic record of health-related information on an individual that:
 - (A) includes patient demographic and clinical health information, such as medical history and problem lists; and
 - (B) has the capacity to:
 - (i) provide clinical decision support;
 - (ii) support physician order entry;
 - (iii) capture and query information relevant to health care quality; and
 - (iv) exchange electronic health information with, and integrate such information from other sources.”

Key Definitions – Complete & Modular EHRs

- **EHR Module** - any service, component, or combination thereof that can meet the requirements of at least one certification criterion adopted by the Secretary.
- **Complete EHR** means an EHR technology that has been developed to meet all applicable certification criteria adopted by the Secretary.

Key Definitions – Certified EHR Technology

A Complete EHR or a combination of EHR Modules, each of which:

- 1) meets the requirements included in the definition of a Qualified EHR; and
- 2) has been tested and certified in accordance with the certification program established by the National Coordinator as having met all applicable certification criteria adopted by the Secretary.

Table 1 – Certification Criteria

Proposed Meaningful Use Stage 1 Objectives	Certification Criteria to Support the Achievement of Meaningful Use Stage 1 by Eligible Professionals	Certification Criteria to Support the Achievement of Meaningful Use Stage 1 by Eligible Hospital
<u>A Complete EHR or EHR Module must include the capability to:</u>		
Use Computerized Provider Order Entry (CPOE) ³	Enable a user to electronically record, store, retrieve, and manage, at a minimum, the following order types: <ol style="list-style-type: none"> 1. Medications; 2. Laboratory; 3. Radiology/imaging; and 4. Provider referrals. 	Enable a user to electronically record, store, retrieve, and manage, at a minimum, the following order types: <ol style="list-style-type: none"> 1. Medications; 2. Laboratory; 3. Radiology/imaging; 4. Blood bank; 5. Physical therapy; 6. Occupational therapy; 7. Respiratory therapy; 8. Rehabilitation therapy; 9. Dialysis; 10. Provider consults; and 11. Discharge and transfer.

Table 2A – Adopted Content Exchange and Vocabulary Standards

<u>Row #</u>	<u>Purpose</u>	<u>Category</u>	<u>Adopted Standard(s) to Support Meaningful Use Stage 1</u>	<u>Candidate Standard(s) to Support Meaningful Use Stage 2</u>
1	<i>Patient Summary Record</i>	Cx	HL7 CDA R2 CCD Level 2 or ASTM CCR	Alternatives expected to be narrowed based on HIT Standards Committee recommendations
	• Problem List	V	Applicable HIPAA code set required by law (i.e., ICD-9-CM); or SNOMED CT®	Applicable HIPAA code set required by law (e.g., ICD-10-CM) or SNOMED CT®
	• Medication List	V	Any code set by an RxNorm drug data source provider that is identified by the United States National Library of Medicine as being a complete data set integrated within RxNorm ⁺	RxNorm
	• Medication Allergy List	V	No standard adopted at this time.	UNII

Table 2B – Adopted Privacy and Security Standards

<u>Row #</u>	<u>Purpose</u>	<u>Adopted Standard</u>
1	<i>General Encryption and Decryption of Electronic Health Information</i>	A symmetric 128 bit fixed-block cipher algorithm capable of using a 128, 192, or 256 bit encryption key must be used (e.g., FIPS 197 Advanced Encryption Standard, (AES), Nov 2001). ⁺
2	<i>Encryption and Decryption of Electronic Health Information for Exchange</i>	An encrypted and integrity protected link must be implemented (e.g., TLS, IPv6, IPv4 with IPsec). ⁺
3	<i>Record Actions Related to Electronic Health Information (i.e., audit log)</i>	The date, time, patient identification (name or number), and user identification (name or number) must be recorded when electronic health information is created, modified, deleted, or printed. An indication of which action(s) occurred must also be recorded (e.g., modification). ⁺
4	<i>Verification that Electronic Health Information has not been Altered in Transit</i>	A secure hashing algorithm must be used to verify that electronic health information has not been altered in transit. The secure hash algorithm used must be SHA-1 or higher (e.g., Federal Information Processing Standards (FIPS) Publication (PUB) Secure Hash Standard (SHS) FIPS PUB 180-3). ⁺
5	<i>Cross-Enterprise Authentication</i>	Use of a cross-enterprise secure transaction that contains sufficient identity information such that the receiver can make access control decisions and produce detailed and accurate security audit trails (e.g., IHE Cross Enterprise User Assertion (XUA) with SAML identity assertions). ⁺
6	<i>Record Treatment, Payment, and Health Care Operations Disclosures</i>	The date, time, patient identification (name or number), user identification (name or number), and a description of the disclosure must be recorded. ⁺

Table 2B on Pages 85 of Standards, Implementation, Specifications, and Certification Criteria for EHR Technology (RIN 0991-AB58) December 2009

Anticipated Regulations

HHS Certification Process - What we can expect:

- **ONC will be establishing an HHS Certification Process for**
 - a) organizations to become certifying bodies and
 - b) health IT solution manufacturers to get systems certified.
- **We anticipate an Interim Final Rule to be released before January 31, 2010**

Meaningful Use and Standards/Certification Criteria Webinar Series

January 13, 2010

Translating from Theory to Practice: Certification Criteria and Standards for Obtaining Meaningful Use

Confirmed Speakers:

John D. Halamka, MD, Chief Information Officer, CareGroup Healthcare System

Mark K. Leavitt, MD, PhD, FHIMSS, CCHIT Chairman

Sponsored by CISCO

January 20, 2010

***Quality Metrics Requirements for Obtaining Meaningful Use:
Developing a Plan for Implementation***

Confirmed Speaker:

Louis H. Diamond, M.B. Ch.B., FACP, VP & Medical Director, Thomson Reuters

Meaningful Use and Standards/Certification Criteria Webinar Series

January 27, 2010

The Economics of ARRA: Understanding Medicare and Medicaid Payments

Confirmed Speaker:

Patricia Wise, RN, MSN, MA, FHIMSS, VP for Healthcare IS, HIMSS

Sponsored by CISCO

February 3, 2010

Privacy and Security: Understanding the Latest Developments

Confirmed Speaker:

Dixie B. Baker, PhD, SVP Health CTO Information & Network Solutions, SAIC

Lisa A. Gallagher, BSEE, CISM, Sr. Director, Privacy & Security, HIMSS

February 10, 2010

Workforce Development: An Industry Update

Resources

- **ONC: <http://healthit.hhs.gov>**
- **CMS: www.cms.hhs.gov**
- **HIMSS: One stop for all ARRA information**
www.himss.org/economicstimulus
 - Summary, Analysis, FAQs
 - RSS Feed, Social Media
 - Tools & Resources
- **Informing the HIMSS response – launched today – give us your opinion and feedback on the drafts**

Examples of Tools & Resources at himss.org/economicstimulus

- **HIMSS10 Sessions on ARRA**
himssconference.org
- **EHR Best Practices**
himss.org/davies/resources.asp
- **Privacy & Security Toolkit**
himss.org/ASP/privacySecurityTree.asp?faid=78&tid=4
- **Selecting the Right EMR Vendor & Online Buyers Guide**
himss.org/content/files/SelectingEMR_Flyer2.pdf
onlinebuyersguide.himss.org/
- **CDS & MU Home Page**
himssclinicaldecisionsupportwiki.pbworks.com/CDS-and-Meaningful-Use-Home-Page