

UPDATE ON STANDARDS: THE FINAL RULE

The Final Meaningful Use Rule: Overview of Changes and Clarifications to Meaningful Use

The final rule for meaningful use incentives for 2011 and 2012 was released on July 13, 2010. The basic shape of the meaningful use rule is unchanged from the draft released in January, but significant flexibility has been added that will make the transition to EHRs more feasible for many providers.

- For 2011 and 2012, the requirements for meaningful use incentives are divided into core requirements that are mandatory and a menu of ten additional requirements of which five need to be met.
- Two new optional requirements have been added.
- The requirements for electronic eligibility checking and claims submission have been eliminated (but will be required under the health reform law).
- The percentage of patients that are required to qualify as a meaningful user have been lowered for many (but not all) criteria.
- The quality reporting requirements have been scaled back.

For more CSC papers and analysis on [Meaningful Use](#) and the [EHR Incentives](#), visit [Health Services Industry Insights](#) on www.csc.com.

Background

On July 13, 2010, the Centers for Medicare & Medicaid Services (CMS) and the Office of the National Coordinator for Health Information Technology (ONC) issued a final rule to complete the adoption of an initial set of standards and implementation specifications for what constitutes a Certified Electronic Health Record (EHR) Technology. The rule establishes the standards to which EHRs will need to adhere in order to support the achievement of meaningful use Stage 1. The [final rule](#) is available online at the U.S. Department of Health and Human Services (HHS) website.

Previously, the Health Information Technology (HIT) Policy Committee and the HIT Standards Committee, operating under the ONC, had proposed an interim set of standards. These were subject to public comments, to which HHS responds in the final ruling document.

The adopted standards are intended to advance healthcare toward higher levels of efficiency, safety and interoperability while being representative of the leading technologies and practices in use in the industry. As expected, the standards and specifications adopted in the final rule closely follow those released in the interim final rule.

(Note: For your convenience, we have included a glossary of acronyms at the end of this paper.)

Vocabulary and Content Exchange Standards

HHS selected the vocabulary standards of ICD-9-CM, SNOMED CT, RxNorm and LOINC. The adopted standard for the problem list in the patient summary record is the applicable HIPAA code set (i.e., ICD-9-CM) or SNOMED CT. Lab results received in LOINC format must be stored and presentable in a human-readable format using LOINC. Acceptable standards for procedures are ICD-9-CM or CPT-4.

The Stage 1 vocabulary, standard for both the medication list and e-prescribing, is “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 with RxNorm.”

No particular standards or code sets were adopted for storing a medication allergy list or vital signs. HHS recognizes that there are multiple valid ways to store these data, and therefore they only require that Certified EHR Technology be capable of doing so. They do not specify how it must be done.

For content exchange standards, providers may use the HL7 Clinical Document Architecture (CDA) Release 2 and the Continuity of Care Document (CCD), or the ASTM E2369 Standard Specification for the Continuity of Care Record (CCR).

The adopted content exchange standards for drug formulary checking and electronic prescribing are from NCPDP. HL7 2.5.1 is required for submission of lab results and other data to public health agencies.

The data transport standards that were proposed in the interim final rule (SOAP and REST) were removed from the final rule. After review, HHS found that specifying these standards would not have ensured interoperability, and in fact could have introduced conflicts at the present time. HHS will revisit this area in the future to see how the industry develops.

The final rule also includes a number of implementation specifications to ensure that standards are implemented in a way that allows for system interoperability. The table below shows the standards and implementation specifications adopted in the final rule.

Category	Specific Area/Type	Stage 1 Standard [Implementation Specification]
Patient Summary Record	Data sharing	HL7 CDA R2 CCD [HITSP Summary Document Using HL7 CCD]; or ASTM CCR
	Problem list	Applicable HIPAA code set (i.e., ICD-9-CM) or SNOMED-CT [IHTSDO July 2009 Version]
	Medication list	Any complete code set that is integrated within RxNorm
	Procedures	Applicable HIPAA code set (i.e., ICD-9-CM or CPT-4)
	Laboratory	LOINC version 2.27 when receiving LOINC codes from laboratory
Drug Formulary Check	Content exchange	Applicable Part D standard (i.e., NCPDP)
Electronic Prescribing	Content exchange	Applicable Part D standard (e.g., NCPDP 8.1) [Implementation Guide Version 8.1] or NCPD SCRIPT [Implementation Guide Version 10.6]
	Vocabulary	Any complete code set that is integrated within RxNorm
Quality Reporting	Content exchange	CMS PQRI 2009 Registry XML Specification [PQRI Manual for Claims and Registry]
Submission to Public Health Agencies	Lab results content	HL7 2.5.1 [HL7 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1]
	Lab results vocabulary	LOINC when receiving LOINC codes from laboratory
	Surveillance or Reporting	HL7 2.3.1 or HL7 2.5.1 [Public Health Information Network HL7 Version 2.5 Message Structure Specification for National Condition Reporting Final Version 1.0]
Submission to Immunization Registries	Content exchange	HL7 2.3.1 [Implementation Guide Version 2.2] or HL7 2.5.1 [Implementation Guide 1.0]
	Vocabulary	HL7 Standard Code Set CVX Vaccines Administered (July 30, 2009 version)

Standards for Privacy and Security

The adopted standards for privacy and security deal with functions such as access control, authentication and data transmission. In order to help hospitals and providers achieve and sustain a common baseline to start, HHS has selected standards that align with existing HIPAA security requirements.

As expected, HHS adopted an encryption standard from the National Institute of Standards and Technology (NIST) to require systems to render protected health information unusable, unreadable or indecipherable to unauthorized individuals. Removed in the final rule was the requirement to perform cross-enterprise authentication, which would have required EHRs to be capable of

verifying user identity access rights to information across organizations. As pointed out by stakeholders during the public comment period, that functionality does not generally reside within the EHR, and it would have been an undue burden on users at the present time.

The following table summarizes the privacy and security standards adopted in the final rule.

Category	Stage 1 Standard
Encryption and Decryption of Electronic Health Information	Any encryption algorithm identified by NIST as an approved security function in Annex A of the Federal Information Processing Standards (FIPS) Publication 140-2
Recording of Action (i.e., access/audit log)	The date, time, patient identification and user identification must be recorded when electronic health information is created, modified, accessed or deleted; and an indication of which action(s) occurred and by whom must also be recorded
Transmission Integrity	A hashing algorithm with a security strength equal to or greater than SHA-1 (Secure Hash Algorithm 1) as specified by NIST in FIPS PUB 180-3 (October, 2008) to verify that electronic health information has not been altered
Accounting of Disclosures	The date, time, patient identification, user identification and a description of the disclosure must be recorded for disclosures for treatment, payment and health care operations, as these terms are defined at 45 CFR 164.501

Future Evolution of Standards

The standards described above have been adopted to support the proposed requirements for meaningful use Stage 1 only. Future rulings will officially determine the standards for later stages, but there is a general expectation that standards will migrate to newer versions as they are released (e.g., from ICD-9-CM to ICD-10-CM for the problem list).

One area of future development will likely be administrative transactions. In the recent ruling, insurance eligibility checking and electronic claims submission were removed from meaningful use. HHS recognizes that in order to meet upcoming administrative simplification deadlines, many providers will need to upgrade or replace their administrative systems, providing an opportunity to align EHR standards across the industry. In the final rule, HHS states, “Therefore, we intend to include for adoption, administrative transactions standards and certification criteria to support meaningful use Stage 2 rulemaking, and expect health care providers and Complete EHR and EHR Module developers to take this into consideration leading up to 2013.”

No strong indications have yet been made regarding the standards for Stage 3. HHS maintains its position that it will be careful not to overprescribe standards and risk inhibiting innovation in the marketplace.

Recommendations

- Hospitals should start migrating to the adopted standards immediately. In order to receive the maximum incentive payment, hospitals must achieve meaningful use of a Certified EHR no later than FY 2013; eligible professionals have until CY 2012. This is a short timeframe to implement the standards needed to achieve meaningful use.
- Understand the ability and commitment of your vendor to achieve certification. Make sure the vendors you plan to use to meet meaningful use have definite plans to get their product certified and that their schedule meets your needs.
- Work towards implementing the Stage 1 standards with an eye to staying on course for the likely Stage 2 standards. Follow generally accepted implementation specifications when possible.



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Mini-Glossary of Acronyms

The interim final rule is rich in acronyms and technical abbreviations. Here is a brief glossary to help make our discussion above more understandable.

Acronym	Name/Term
ICD-9-CM	International Classification of Diseases, 9th Edition, Clinical Modifications
ICD-10-CM	International Classification of Diseases, 10th Edition, Clinical Modifications
SNOMED CT	Systematized Nomenclature of Medicine, Clinical Terms
LOINC	Logical Observation Identifiers Names and Codes
CPT-4	Current Procedural Terminology, 4th Edition
CCD	Continuity of Care Document
CCR	Continuity of Care Record
NCPDP	National Council for Prescription Drug Programs
HITSP	Health Information Technology Standards Panel
HL7	Health Level 7
IHTSDO	International Health Terminology Standards Development Organization
SOAP	Simple Object Access Protocol
REST	Representational State Transfer
PQRI	Physician Quality Reporting Initiative
TLS	Transport Layer Security
IPv6/IPv4	Internet Protocol version 6/Internet Protocol version 4
UCUM	Unified Code for Units of Measure

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