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DEFINING SUCCESS TOGETHER

HIT Standards, Implementation Specifications and Certification Criteria

Overview of ONC Interim Final Rule

Jane Eckels
Partner, Health Information Technology Group

Interim Final Rule

- Published January 13, 2010
- 60 day public comment period
- Effective 30 days after publication, during comment period
- Final rule anticipated in Spring 2010

Scope

- Designed directly to support the meaningful use certification criteria for eligible providers and hospitals
- Covers Stage 1 only
- EHR certification program and process to become a certifying body will be subject of future rulemaking

Certified EHR Technology

- Meets the requirements of a “Qualified EHR”
- Has been tested and certified in accordance with the certification program established by the ONC as having met all certification criteria

Complete EHR v. EHR Modules

- Complete EHR: All-in-one EHR solution that meets all criteria
- EHR Module: Any service, component or combination thereof that meets at least one criterion
  - May include, e.g., software as service, interface allowing participation in health information exchange, quality measure reporting service

EHR Modules

- It is the responsibility of the ***eligible provider or hospital*** for a proper combination of EHR Modules
  - Certification of combinations is not required
  - Each EHR Module must be certified
  - Each and every criterion for Certified EHR Technology must be certified

Standards

- Information transmission
  - communications protocols
- Vocabularies:
  - nomenclatures and code sets for clinical problems and procedures, medications and allergies
- Content exchange:
  - sharing clinical information, such as clinical summaries, prescriptions, structured electronic documents
- Privacy and Security:
  - authentication, access control, transmission security

Standards

- Designed to adopt standards currently in use
  - Information transport standards used in the technology industry generally (SOAP 1.2, REST)
  - Vocabularies, content and privacy/security standards currently used in the healthcare industry
- Standards will evolve over time
  - Identifies anticipated standards for Stage 2
  - Alternate standards are anticipated to converge to a single standard in the future
  - “At a minimum” standards designed to allow use of newer, updated standards
    - E.g., subsequently released version of a code set
- Consistent with HIPAA transaction and code set requirements and their implementation timeline

Content and Vocabulary Standards

TABLE 2A—ADOPTED CONTENT EXCHANGE AND VOCABULARY STANDARDS

Row No.	*Purpose*	*Category*	*Adopted standard(s) to support meaningful use stage 1*	*Candidate standard(s) to support meaningful use stage 2*
1	*Patient Summary Record*	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.
	• Procedures	V	Applicable HIPAA code sets required by law (i.e., ICD–9–CM or CPT–4®).	Applicable HIPAA code sets required by law (*i.e.*, ICD–10–PCS or CPT–4®).
	• Vital Signs	V	No standard adopted at this time	CDA template.
	• Units of Measure	V	No standard adopted at this time	UCUM.
	• Lab Orders and Results	V	LOINC® when LOINC® codes have been received from a laboratory.	LOINC®.
2	*Drug Formulary Check*	Cx	Applicable Part D standard required by law (i.e., NCPDP Formulary & Benefits Standard 1.0).	Applicable Part D standard required by law.
3	*Electronic Prescribing*	Cx	Applicable Part D standard required by law (e.g., NCPDP SCRIPT 8.1) or NCPDP SCRIPT 8.1 and NCPDP SCRIPT 10.6.	NCPDP SCRIPT 10.6.
		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.

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Content and Vocabulary Standards

TABLE 2A—ADOPTED CONTENT EXCHANGE AND VOCABULARY STANDARDS—Continued

Row No.	*Purpose*	*Category*	*Adopted standard(s) to support meaningful use stage 1*	*Candidate standard(s) to support meaningful use stage 2*
4	*Administrative Transactions*	Cx	Applicable HIPAA transaction standards required by law.	Applicable HIPAA transaction standards required by law.
5	*Quality Reporting*	Cx	CMS PQRI 2008 Registry XML Specification [#,+].	Potentially newer version(s) or standards based on HIT Standards Committee Input.
6	*Submission of Lab Results to Public Health Agencies.*	Cx	HL7 2.5.1	Potentially newer version(s) or standards based on HIT Standards Committee Recommendations.
		V	LOINC® when LOINC® codes have been received from a laboratory.	LOINC®, UCUM, and SNOMED CT® or Applicable Public Health Agency Requirements.
7	*Submission to Public Health Agencies for Surveillance or Reporting (excluding adverse event reporting).*	Cx	HL7 2.3.1 or HL7 2.5.1	Potentially newer version(s) or standards based on HIT Standards Committee Input.
		V	According to Applicable Public Health Agency Requirements.	GIPSE or According to Applicable Public Health Agency Requirements.
8	*Submission to Immunization Registries.*	Cx	HL7 2.3.1 or HL7 2.5.1	Potentially newer version(s) or standards based on HIT Standards Committee Recommendations.
		V	CVX[*,+]	CVX.

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Privacy and Security Standards

TABLE 2B—ADOPTED PRIVACY AND SECURITY STANDARDS

Row No.	*Purpose*	*Adopted standard*
1	*General Encryption and Decryption of Electronic Health Information.*	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	*Encryption and Decryption of Electronic Health Information for Exchange.*	An encrypted and integrity protected link must be implemented (*e.g.,* TLS, IPv6, IPv4 with IPsec).+
3	*Record Actions Related to Electronic Health Information (i.e., audit log).*	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	*Verification that Electronic Health Information has not been Altered in Transit.*	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	*Cross-Enterprise Authentication*	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	*Record Treatment, Payment, and Health Care Operations Disclosures.*	The date, time, patient identification (name or number), user identification (name or number), and a description of the disclosure must be recorded.+

Certification Criteria

- Tracks meaningful use criteria set out in CMS proposed rulemaking
- Areas of general applicability
- Distinct criteria specific to inpatient and ambulatory settings
- Future rulemaking anticipated with respect to ED and specialty EHRs

Certification Criteria

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
	A Complete EHR or EHR Module must include the capability to:	
Use Computerized Provider Order Entry (CPOE) [3].	Enable a user to electronically record, store, retrieve, and manage, at a minimum, the following order types: 1. Medications; 2. Laboratory; 3. Radiology/imaging; and	Enable a user to electronically record, store, retrieve, and manage, at a minimum, the following order types: 1. Medications; 2. Laboratory; 3. Radiology/imaging;
	4. Provider referrals.	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.

Certification Criteria

TABLE 1—CERTIFICATION CRITERIA—Continued

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
Implement drug-drug, drug-allergy, drug-formulary checks.	1. Automatically and electronically generate and indicate (*e.g.*, pop-up message or sound) in real-time, alerts at the point of care for drug-drug and drug-allergy contraindications based on medication list, medication allergy list, age, and CPOE. 2. Enable a user to electronically check if drugs are in a formulary or preferred drug list in accordance with the standard specified in Table 2A row 2. 3. Provide certain users with administrator rights to deactivate, modify, and add rules for drug-drug and drug-allergy checking. 4. Automatically and electronically track, record, and generate reports on the number of alerts responded to by a user.	
Maintain an up-to-date problem list of current and active diagnoses based on ICD–9–CM or SNOMED CT®.	Enable a user to electronically record, modify, and retrieve a patient's problem list for longitudinal care (*i.e.*, over multiple office visits) in accordance with the applicable standards% specified in Table 2A row 1.	
Generate and transmit permissible prescriptions electronically (eRx).	Enable a user to electronically transmit medication orders (prescriptions) for patients in accordance with the standards specified in Table 2A row 3.	No Associated Proposed Meaningful Use Stage 1 Objective.
Maintain active medication list	Enable a user to electronically record, modify, and retrieve a patient's active medication list as well as medication history for longitudinal care (*i.e.*, over multiple office visits) in accordance with the applicable standard specified in Table 2A row 1.	
Maintain active medication allergy list	Enable a user to electronically record, modify, and retrieve a patient's active medication allergy list as well as medication allergy history for longitudinal care (*i.e.*, over multiple office visits).	

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Certification Criteria

TABLE 1—CERTIFICATION CRITERIA—Continued

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
Record demographics [4 5]	Enable a user to electronically record, modify, and retrieve patient demographic data including preferred language, insurance type, gender, race, ethnicity, and date of birth.	Enable a user to electronically record, modify, and retrieve patient demographic data including preferred language, insurance type, gender, race, ethnicity, date of birth, and date and cause of death in the event of mortality.
Record and chart changes in vital signs: • Height • Weight • Blood pressure • Calculate and display: BMI • Plot and display growth charts for children 2–20 years, including BMI.	1. Enable a user to electronically record, modify, and retrieve a patient's vital signs including, at a minimum, the height, weight, blood pressure, temperature, and pulse. 2. Automatically calculate and display body mass index (BMI) based on a patient's height and weight. 3. Plot and electronically display, upon request, growth charts (height, weight, and BMI) for patients 2–20 years old.	
Record smoking status for patients 13 years old or older.	Enable a user to electronically record, modify, and retrieve the smoking status of a patient to: current smoker, former smoker, or never smoked.	
Incorporate clinical lab-test results into EHR as structured data.	1. Electronically receive clinical laboratory test results in a structured format and display such results in human readable format. 2. Electronically display in human readable format any clinical laboratory tests that have been received with LOINC® codes. 3. Electronically display all the information for a test report specified at 42 CFR 493.1291(c)(1) through (7).[6] 4. Enable a user to electronically update a patient's record based upon received laboratory test results.	
Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, and outreach.	Enable a user to electronically select, sort, retrieve, and output a list of patients and patients' clinical information, based on user-defined demographic data, medication list, and specific conditions.	
Report quality measures to CMS or the States [7 8].	1. Calculate and electronically display quality measure results as specified by CMS or states. 2. Enable a user to electronically submit calculated quality measures in accordance with the standard specified in Table 2A row 5.	

Certification Criteria

TABLE 1—CERTIFICATION CRITERIA—Continued

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
Send reminders to patients per patient preference for preventive/follow up care.	Electronically generate, upon request, a patient reminder list for preventive or follow-up care according to patient preferences based on demographic data, specific conditions, and/or medication list.	No Associated Proposed Meaningful Use Stage 1 Objective.
Implement 5 clinical decision support rules[9,10]	1. Implement automated, electronic clinical decision support rules (in addition to drug-drug and drug-allergy contraindication checking) according to specialty or clinical priorities that use demographic data, specific patient diagnoses, conditions, diagnostic test results and/or patient medication list. 2. Automatically and electronically generate and indicate (*e.g.,* pop-up message or sound) in real-time, alerts and care suggestions based upon clinical decision support rules and evidence grade. 3. Automatically and electronically track, record, and generate reports on the number of alerts responded to by a user.	1. Implement automated, electronic clinical decision support rules (in addition to drug-drug and drug-allergy contraindication checking) according to a high priority hospital condition that use demographic data, specific patient diagnoses, conditions, diagnostic test results and/or patient medication list. 2. Automatically and electronically generate and indicate (*e.g.,* pop-up message or sound) in real-time, alerts and care suggestions based upon clinical decision support rules and evidence grade. 3. Automatically and electronically track, record, and generate reports on the number of alerts responded to by a user.
Check insurance eligibility electronically from public and private payers.	Enable a user to electronically record and display patients' insurance eligibility, and submit insurance eligibility queries to public or private payers and receive an eligibility response in accordance with the applicable standards specified in Table 2A row 4.	
Submit claims electronically to public and private payers.	Enable a user to electronically submit claims to public or private payers in accordance with the applicable standards specified in Table 2A row 4.	

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Certification Criteria

TABLE 1—CERTIFICATION CRITERIA—Continued

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
Provide patients with an electronic copy of their health information upon request [11 12].	Enable a user to create an electronic copy of a patient's clinical information, including, at a minimum, diagnostic test results, problem list, medication list, medication allergy list, immunizations, and procedures in: (1) Human readable format; and (2) accordance with the standards[%] specified in Table 2A row 1 to provide to a patient on electronic media, or through some other electronic means.	Enable a user to create an electronic copy of a patient's clinical information, including, at a minimum, diagnostic test results, problem list, medication list, medication allergy list, immunizations, discharge summary, and procedures in: (1) Human readable format; and (2) accordance with the standards[%] specified in Table 2A row 1 to provide to a patient on electronic media, or through some other electronic means.
Provide patients with an electronic copy of their discharge instructions and procedures at time of discharge, upon request.	No Associated Proposed Meaningful Use Stage 1 Objective.	Enable a user to create an electronic copy of the discharge instructions and procedures for a patient, in human readable format, at the time of discharge to provide to a patient on electronic media, or through some other electronic means.
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 eligible professional.	Enable a user to provide patients with online access to their clinical information, including, at a minimum, lab test results, problem list, medication list, medication allergy list, immunizations, and procedures.	No Associated Proposed Meaningful Use Stage 1 Objective.
Provide clinical summaries for patients for each office visit.	1. Enable a user to provide clinical summaries to patients (in paper or electronic form) for each office visit that include, at a minimum, diagnostic test results, medication list, medication allergy list, procedures, problem list, and immunizations. 2. If the clinical summary is provided electronically (*i.e.,* not printed), it must be provided in: (1) Human readable format; and (2) accordance with the standards[%] specified in Table 2A row 1 to provide to a patient on electronic media, or through some other electronic means.	No Associated Proposed Meaningful Use Stage 1 Objective.

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Certification Criteria

TABLE 1—CERTIFICATION CRITERIA—Continued

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
Provide patients with an electronic copy of their health information upon request[11 12].	Enable a user to create an electronic copy of a patient's clinical information, including, at a minimum, diagnostic test results, problem list, medication list, medication allergy list, immunizations, and procedures in: (1) Human readable format; and (2) accordance with the standards[%] specified in Table 2A row 1 to provide to a patient on electronic media, or through some other electronic means.	Enable a user to create an electronic copy of a patient's clinical information, including, at a minimum, diagnostic test results, problem list, medication list, medication allergy list, immunizations, discharge summary, and procedures in: (1) Human readable format; and (2) accordance with the standards[%] specified in Table 2A row 1 to provide to a patient on electronic media, or through some other electronic means.
Provide patients with an electronic copy of their discharge instructions and procedures at time of discharge, upon request.	No Associated Proposed Meaningful Use Stage 1 Objective.	Enable a user to create an electronic copy of the discharge instructions and procedures for a patient, in human readable format, at the time of discharge to provide to a patient on electronic media, or through some other electronic means.
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 eligible professional.	Enable a user to provide patients with online access to their clinical information, including, at a minimum, lab test results, problem list, medication list, medication allergy list, immunizations, and procedures.	No Associated Proposed Meaningful Use Stage 1 Objective.
Provide clinical summaries for patients for each office visit.	1. Enable a user to provide clinical summaries to patients (in paper or electronic form) for each office visit that include, at a minimum, diagnostic test results, medication list, medication allergy list, procedures, problem list, and immunizations. 2. If the clinical summary is provided electronically (*i.e.*, not printed), it must be provided in: (1) Human readable format; and (2) accordance with the standards[%] specified in Table 2A row 1 to provide to a patient on electronic media, or through some other electronic means.	No Associated Proposed Meaningful Use Stage 1 Objective.

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Certification Criteria

TABLE 1—CERTIFICATION CRITERIA—Continued

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
Capability to exchange key clinical information among providers of care and patient authorized entities electronically [13] [14]. Provide summary care record for each transition of care and referral.	1. Electronically receive a patient summary record, from other providers and organizations including, at a minimum, diagnostic test results, problem list, medication list, medication allergy list, immunizations, and procedures and upon receipt of a patient summary record formatted in an alternative standard specified in Table 2A row 1, displaying it in human readable format. 2. Enable a user to electronically transmit a patient summary record to other providers and organizations including, at a minimum, diagnostic test results, problem list, medication list, medication allergy list, immunizations, and procedures in accordance with the standards[%] specified in Table 2A row 1.	1. Electronically receive a patient summary record, from other providers and organizations including, at a minimum, discharge summary, diagnostic test results, problem list, medication list, medication allergy list, immunizations, and procedures and upon receipt of a patient summary record formatted in an alternative standard specified in Table 2A row 1, displaying it in human readable format. 2. Enable a user to electronically transmit a patient summary record, to other providers and organizations including, at a minimum, discharge summary, diagnostic test results, problem list, medication list, medication allergy list, immunizations, and procedures in accordance with the standards[%] specified in Table 2A row 1.
Perform medication reconciliation at relevant encounters and each transition of care. Capability to submit electronic data to immunization registries and actual submission where required and accepted.	Electronically complete medication reconciliation of two or more medication lists (compare and merge) into a single medication list that can be electronically displayed in real-time. Electronically record, retrieve, and transmit immunization information to immunization registries in accordance with the standards[%] specified in Table 2A row 8 or in accordance with the applicable state-designated standard format.	
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.	No Associated Proposed Meaningful Use Stage 1 Objective.	Electronically record, retrieve, and transmit reportable clinical lab results to public health agencies in accordance with the standards[%] specified in Table 2A row 6.

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Certification Criteria

TABLE 1—CERTIFICATION CRITERIA—Continued

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
Capability to provide electronic syndromic surveillance data to public health agencies and actual transmission according to applicable law and practice.	Electronically record, retrieve, and transmit syndrome-based (*e.g.,* influenza like illness) public health surveillance information to public health agencies in accordance with the standards specified in Table 2A row 7.	
Protect electronic health information created or maintained by the certified EHR technology through the implementation of appropriate technical capabilities.	1. Assign a unique name and/or number for identifying and tracking user identity and establish controls that permit only authorized users to access electronic health information. 2. Permit authorized users (who are authorized for emergency situations) to access electronic health information during an emergency. 3. Terminate an electronic session after a predetermined time of inactivity. 4. Encrypt and decrypt electronic health information according to user-defined preferences (*e.g.,* backups, removable media, at log-on/off) in accordance with the standard specified in Table 2B row 1. 5. Encrypt and decrypt electronic health information when exchanged in accordance with the standard specified in Table 2B row 2. 6. Record actions (*e.g.,* deletion) related to electronic health information in accordance with the standard specified in Table 2B row 3 (*i.e.,* audit log), provide alerts based on user-defined events, and electronically display and print all or a specified set of recorded information upon request or at a set period of time. 7. Verify that electronic health information has not been altered in transit and detect the alteration and deletion of electronic health information and audit logs in accordance with the standard specified in Table 2B row 4. 8. Verify that a person or entity seeking access to electronic health information is the one claimed and is authorized to access such information. 9. Verify that a person or entity seeking access to electronic health information across a network is the one claimed and is authorized to access such information in accordance with the standard specified in Table 2B row 5. 10. Record disclosures made for treatment, payment, and health care operations in accordance with the standard specified in Table 2B row 6.	

No Guarantee of Compliance

- Does not change HIPAA privacy rule or security rule requirements
- Does not guarantee HIPAA compliance
- Does not waive compliance requirements
- Same is true for any other legal requirements

Questions?

Jane Eckels
Davis Wright Tremaine LLP
1201 Third Avenue, Suite 2200
Seattle, Washington 98101
(206) 757-8037
janeeckels@dwt.com