# Test Procedure for §170.302 (w) Optional. Accounting of Disclosures

This document describes the test procedure for evaluating conformance of complete EHRs or EHR modules[1] to the certification criteria defined in 45 CFR Part 170 Subpart C of the Final Rule for Health Information Technology: Initial Set of standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology as published in the Federal Register on July 28, 2010. The document[2] is organized by test procedure and derived test requirements with traceability to the normative certification criteria as described in the Overview document located at http://healthcare.nist.gov/docs/TestProcedureOverview_v1.pdf. The test procedures may be updated to reflect on-going feedback received during the certification activities.

The HHS/Office of the National Coordinator for Health Information Technology (ONC) has defined the standards, implementation guides and certification criteria used in this test procedure. Applicability and interpretation of the standards, implementation guides and certification criteria to EHR technology is determined by ONC. Test procedures to evaluate conformance of EHR technology to ONC's requirements are defined by NIST. Testing of EHR technology is carried out by ONC-Authorized Testing and Certification Bodies (ATCBs), not NIST, as set forth in the final rule establishing the Temporary Certification Program (*Establishment of the Temporary Certification Program for Health Information Technology, 45 CFR Part 170; June 24, 2010*.)

Questions about the applicability of the standards, implementation guides or criteria should be directed to ONC at ONC.Certification@hhs.gov. Questions about the test procedures should be directed to NIST at hit-tst-fdbk@nist.gov. Note that NIST will automatically forward to ONC any questions regarding the applicability of the standards, implementation guides or criteria. Questions about functions and activities of the ATCBs should be directed to ONC at ONC.Certification@hhs.gov .

## CERTIFICATION CRITERIA

This Certification Criterion is from the Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology Final Rule issued by the Department of Health and Human Services (HHS) on July 28, 2010.

§170.302(w) Optional. Accounting of disclosures. Record disclosures made for treatment, payment, and healthcare operations in accordance with the standards specified in §170.210(d).

Per Section III.D of the preamble of the Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, Final Rule where the accounting of disclosures certification criterion is discussed:

[1] Department of Health and Human Services, 45 CFR Part 170 Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, Final Rule, July 28, 2010.

[2] Disclaimer: Certain commercial products are identified in this document. Such identification does not imply recommendation or endorsement by the National Institute of Standards and Technology.

- ”As an optional certification criterion, Complete EHR or EHR Modules will not be required to possess the capability for certification.”

## INFORMATIVE TEST DESCRIPTION

This section provides an informative description of how the test procedure is organized and conducted. It is not intended to provide normative statements of the certification requirements.

This test evaluates the capability for a Complete EHR or EHR Module to record treatment, payment, and health care operations 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.

The Vendor supplies the test data for this test procedure.

This test procedure is organized into one section:

- Record disclosures – evaluates the capability to enter treatment, payment, and health care operations disclosures into the EHR
  - The Tester enters the treatment, payment, and health care operations disclosures
  - The Tester validates that the date, time, patient identification, user identification, and a description of the disclosure is recorded for each disclosure

## REFERENCED STANDARDS

| §170.210(d) | Regulatory Referenced Standard |
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| *Record treatment, payment, and health care operations 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. | 45 CFR 164.501<br>As used in this subpart, the following terms have the following meanings:<br>*Correctional institution* means any penal or correctional facility, jail, reformatory, detention center, work farm, halfway house, or residential community program center operated by, or under contract to, the United States, a State, a territory, a political subdivision of a State or territory, or an Indian tribe, for the confinement or rehabilitation of persons charged with or convicted of a criminal offense or other persons held in lawful custody. *Other persons* held in lawful custody includes juvenile offenders adjudicated delinquent, aliens detained awaiting deportation, persons committed to mental institutions through the criminal justice system, witnesses, or others awaiting charges or trial.<br>*Data aggregation* means, with respect to protected health information created or received by a business associate in its capacity as the business associate of a covered entity, the combining of such protected health information by the business associate |

with the protected health information received by the business associate in its capacity as a business associate of another covered entity, to permit data analyses that relate to the health care operations of the respective covered entities.

*Designated record set* means: (1) A group of records maintained by or for a covered entity that is: (i) The medical records and billing records about individuals maintained by or for a covered health care provider; (ii) The enrollment, payment, claims adjudication, and case or medical management record systems maintained by or for a health plan; or (iii) Used, in whole or in part, by or for the covered entity to make decisions about individuals.

(2) For purposes of this paragraph, the term record means any item, collection, or grouping of information that includes protected health information and is maintained, collected, used, or disseminated by or for a covered entity.

*Direct treatment relationship* means a treatment relationship between an individual and a health care provider that is not an indirect treatment relationship.

*Health care operations* means any of the following activities of the covered entity to the extent that the activities are related to covered functions: (1) Conducting quality assessment and improvement activities, including outcomes evaluation and development of clinical guidelines, provided that the obtaining of generalizable knowledge is not the primary purpose of any studies resulting from such activities; population- based activities relating to improving health or reducing health care costs, protocol development, case management and care coordination, contacting of health care providers and patients with information about treatment alternatives; and related functions that do not include treatment; (2) Reviewing the competence or qualifications of health care professionals, evaluating practitioner and provider performance, health plan performance, conducting training programs in which students, trainees, or practitioners in areas of health care learn under supervision to practice or improve their skills as health care providers, training of non-health care professionals, accreditation, certification, licensing, or credentialing activities; (3) Underwriting, premium rating, and other activities relating to the creation, renewal or replacement of a contract of health insurance or health benefits, and ceding, securing, or placing a contract for reinsurance of risk relating to claims for health care (including stop-loss insurance and excess of loss insurance), provided that the requirements of § 164.514(g) are met, if applicable; (4) Conducting or arranging for medical review, legal services, and auditing functions, including fraud and abuse detection and compliance programs; (5) Business planning and development, such as

conducting cost-management and planning-related analyses related to managing and operating the entity, including formulary development and administration, development or improvement of methods of payment or coverage policies; and (6) Business management and general administrative activities of the entity, including, but not limited to: (i) Management activities relating to implementation of and compliance with the requirements of this subchapter; (ii) Customer service, including the provision of data analyses for policy holders, plan sponsors, or other customers, provided that protected health information is not disclosed to such policy holder, plan sponsor, or customer. (iii) Resolution of internal grievances; (iv) The sale, transfer, merger, or consolidation of all or part of the covered entity with another covered entity, or an entity that following such activity will become a covered entity and due diligence related to such activity; and (v) Consistent with the applicable requirements of § 164.514, creating deidentified health information or a limited data set, and fundraising for the benefit of the covered entity.

*Health oversight agency* means an agency or authority of the United States, a State, a territory, a political subdivision of a State or territory, or an Indian tribe, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is authorized by law to oversee the health care system (whether public or private) or government programs in which health information is necessary to determine eligibility or compliance, or to enforce civil rights laws for which health information is relevant.

*Indirect treatment relationship* means a relationship between an individual and a health care provider in which: (1) The health care provider delivers health care to the individual based on the orders of another health care provider; and (2) The health care provider typically provides services or products, or reports the diagnosis or results associated with the health care, directly to another health care provider, who provides the services or products or reports to the individual.

*Inmate* means a person incarcerated in or otherwise confined to a correctional institution.

*Marketing* means: (1) To make a communication about a product or service that encourages recipients of the communication to purchase or use the product or service, unless the communication is made: (i) To describe a health-related product or service (or

payment for such product or service) that is provided by, or included in a plan of benefits of, the covered entity making the communication, including communications about: the entities participating in a health care provider network or health plan network; replacement of, or enhancements
to, a health plan; and health-related products or services available only to a health plan enrollee that add value to, but are not part of, a plan of benefits. (ii) For treatment of the individual; or (iii) For case management or care coordination for the individual, or to direct or recommend alternative treatments, therapies, health care providers, or settings of care to the individual. (2) An arrangement between a covered entity and any other entity
whereby the covered entity discloses protected health information to the other entity, in exchange for direct or indirect remuneration, for the other entity or its affiliate to make a communication about its own product or service that encourages recipients of the communication to purchase or use that product or service.
*Payment* means: (1) The activities undertaken by: (i) A health plan to obtain premiums or to determine or fulfill its responsibility for coverage and provision of
benefits under the health plan; or (ii) A health care provider or health plan to obtain or provide reimbursement for the provision of health care; and (2) The activities in paragraph (1) of this definition relate to the individual to whom health care is provided and include, but are not limited to: (i) Determinations of eligibility or coverage (including coordination of benefits or the determination of cost
sharing amounts), and adjudication or subrogation of health benefit claims; (ii) Risk adjusting amounts due based
on enrollee health status and demographic characteristics; (iii) Billing, claims management, collection activities, obtaining payment under a contract for reinsurance (including stop-loss insurance and excess of loss insurance), and related health care data processing; (iv) Review of health care services with respect to medical necessity, coverage under a health plan, appropriateness of care, or justification of charges; (v) Utilization review activities, including precertification and preauthorization of services, concurrent and retrospective review of services; and (vi) Disclosure to consumer reporting agencies of any of the following protected health information relating to collection of premiums or reimbursement:
(A) Name and address;
(B) Date of birth;
(C) Social security number;
(D) Payment history;
(E) Account number; and
(F) Name and address of the health care

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| | provider and/or health plan.<br>*Psychotherapy notes* means notes recorded (in any medium) by a health care provider who is a mental health<br>professional documenting or analyzing the contents of conversation during a private counseling session or a group,<br>joint, or family counseling session and that are separated from the rest of the individual's medical record. P*sychotherapy notes* excludes medication prescription<br>and monitoring, counseling session start and stop times, the modalities and frequencies of treatment furnished, results of clinical tests, and any summary of the following items: Diagnosis, functional status, the treatment plan, symptoms, prognosis, and progress to date.<br>*Public health authority* means an agency or authority of the United States, a State, a territory, a political subdivision of a State or territory, or an Indian tribe, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is responsible for public health matters as part of its official mandate.<br>*Research* means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.<br>*Treatment* means the provision, coordination, or management of health care and related services by one or more health care providers, including the coordination or management of health care by a health care provider with a third party; consultation between health care providers relating to a patient; or the referral of a patient for health care from one health care provider to another. |

## NORMATIVE TEST PROCEDURES

**Derived Test Requirements**

DTR170.302.w – 1: Record disclosures

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Required Vendor Information

VE170.302.w – 1.01: Vendor shall identify the EHR function(s) that are available to record disclosures for treatment, payment, and health care operations

VE170.302.w – 1.02: Vendor shall identify an existing patient record in the EHR to be used for this test

Required Test Procedure:

TE170.302.w – 1.01: Using the EHR function(s) identified by the Vendor, the Tester shall enter the treatment, payment, and health care operations disclosures test data

TE170.302.w – 1.02: The Tester shall save the treatment, payment, and health care operations disclosures test data

TE170.302.w – 1.03: Using the NIST-supplied Inspection Test Guide, the Tester shall verify that each disclosure has been recorded correctly

Inspection Test Guide:

IN170.302.w – 1.01: Tester shall verify that each disclosure has been recorded correctly and that the following elements have been recorded for each disclosure:

- Date
- Time
- Patient Identification
- User Identification
- Description of the disclosure

## TEST DATA

This Test Procedure requires the vendor to supply the test data. The Tester shall address the following:

- Vendor-supplied test data shall ensure that the functional and interoperable requirements identified in the criterion can be adequately evaluated for conformance
- Vendor-supplied test data shall strictly focus on meeting the basic capabilities required of an EHR relative to the certification criterion rather than exercising the full breadth/depth of capability that an installed EHR might be expected to support
- Tester shall record as part of the test documentation the specific Vendor-supplied test data that was utilized for testing

## CONFORMANCE TEST TOOLS

None

# Document History

| Version Number | Description of Change | Date Published |
|---|---|---|
| 0.3 | Original draft version | April 9, 2010 |
| 1.0 | Updated to reflect Final Rule | July 21, 2010 |
| 1.0 | Updated to remove “Pending” in header | August 13, 2010 |
| 1.1 | Removed “draft” from introductory paragraph<br>Updated numbering scheme | September 24, 2010 |