Test Procedure for §170.314(d)(9) Accounting of disclosures – optional

This document describes the test procedure for evaluating conformance of electronic health record (EHR) technology to the certification criteria defined in 45 CFR Part 170 Subpart C of the Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology, Final Rule. The document[1] 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://www.healthit.gov/certification (navigation: 2014 Edition Test Method). The test procedures may be updated to reflect on-going feedback received during the certification activities.

The Department of Health and Human Services (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. Testing of EHR technology in the Permanent Certification Program, henceforth referred to as the ONC Health Information Technology (HIT) Certification Program[2], is carried out by National Voluntary Laboratory Accreditation Program (NVLAP)-Accredited Testing Laboratories (ATLs) as set forth in the final rule establishing the Permanent Certification Program (*Establishment of the Permanent Certification Program for Health Information Technology, 45 CFR Part 170; February 7, 2011*).

Questions or concerns regarding the ONC HIT Certification Program should be directed to ONC at ONC.Certification@hhs.gov.

CERTIFICATION CRITERION

This certification criterion is from the Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology, Final Rule issued by the Department of Health and Human Services (HHS) on September 4, 2012.

§170.314(d)(9) Optional – Accounting of disclosures. Record disclosures made for treatment, payment, and health care operations in accordance with the standards specified in §170.210(d).

Per Section III.A of the preamble of the Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology, Final Rule, the 2014 Edition of

[1] Disclaimer: Certain commercial products may be identified in this document. Such identification does not imply recommendation or endorsement by ONC.

[2] Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology, Final Rule.

this certification criterion is classified as unchanged without refinements from the 2011 Edition. This certification criterion meets the three factors of unchanged certification criteria: (1) the certification criterion includes only the same capabilities that were specified in previously adopted certification criteria, (2) the certification criterion's capabilities apply to the same setting as they did in previously adopted certification criteria, and (3) the certification criterion remains designated as "mandatory," or it is re-designated as "optional," for the same setting for which it was previously adopted certification criterion.

2014 EDITION PREAMBLE LANGUAGE

Per Section III.A of the preamble of the Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology, Final Rule (September 4, 2012) where the accounting of disclosures certification criterion is discussed:

- "…we agree with those commenters that recommended we wait and consider how best to align this certification criterion with the provisions of an "accounting of disclosures" final rule issued by OCR. We appreciate the suggested revisions offered by commenters, but believe that alignment with an "accounting of disclosures" final rule will provide the most certainty and useful functionality for EPs, EHs, and CAHs, while also mitigating any EHR technology development and implementation burdens that may accrue through compliance with potential multiple adopted versions of this certification criterion."
- "We clarify for commenters that each disclosure that has been recorded must be done so in accordance with the standard at § 170.210(d) and must include the date, time, patient identification, user identification and the description of each disclosure. As to the commenter's question about whether this information could be captured in free text, we expect that date, time, patient identification, and user identification would be automatically recorded only by EHR technology."
- "With respect to the description of each disclosure, we reiterate what we stated in the S&CC July 2010 Final Rule in response to this question (75 FR 44624). 'As we discussed in the Interim Final Rule, we intended to leave Complete EHR and EHR Module developers with the flexibility to innovate in this area and to develop new solutions to address the needs of their customers. We anticipated that a 'description of the disclosure' would, at the present time, be a free text field that would have included any information that could be readily and electronically associated with the disclosure. For example, we envisioned that some descriptive information could be included such as the words 'treatment,' 'payment,' or 'health care operations' separately or together as a general category.'"

2011 Edition Preamble Language

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 (July 28, 2010) where the accounting of disclosures certification criterion is discussed:

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

Changes From 2011 To 2014 Edition

Per Section III.A of the preamble of the Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology, Final Rule (September 4, 2012) where the accounting of disclosures certification criterion is discussed:

- "We proposed to include the following unchanged certification criteria in the 2014 Edition EHR certification criteria without any substantial refinements, except, where appropriate, replacing the terms "generate," "modify," and "retrieve" with "create," "change," and "access," respectively."

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 EHR technology 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 date, time, patient identification, and user identification should be automatically recorded only by EHR technology.

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 verifies that the date, time, patient identification, user identification, and a description of the disclosure are recorded for each disclosure
    - The Tester verifies that the date, time, patient identification, and user identification are recorded automatically for each disclosure

REFERENCED STANDARDS

§170.210 Standards for health information technology to protect electronic health information created, maintained, and exchanged	Regulatory Referenced Standard
The Secretary adopts the following standards to protect electronic health information created, maintained, and exchanged:	
(d) 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 As used in this subpart, the following terms have the following meanings: *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. *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 de-identified 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 provider and/or health plan. *Psychotherapy notes* means notes recorded (in any medium) by a health care provider who is a mental health professional documenting or analyzing the contents of conversation during a private counseling session or a group, joint, or family counseling session and that are separated from the rest of the individual's medical record. P*sychotherapy notes* excludes medication prescription 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. *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. *Research* means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. *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

DTR170.314(d)(9) – 1: Record Disclosures

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Required Vendor Information

VE170.314(d)(9) – 1.01: Vendor shall identify the EHR function(s) that are available to record disclosures for treatment, payment, and health care operations

VE170.314(d)(9) – 1.02: Vendor shall identify an existing patient record in the EHR to be used for this test

Required Test Procedure

TE170.314(d)(9) – 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

TE170.314(d)(9) – 1.02: The Tester shall save the treatment, payment, and health care operations disclosures test data

TE170.314(d)(9) – 1.03: Using the Inspection Test Guide (below), the Tester shall verify that each disclosure has been recorded correctly

Inspection Test Guide

IN170.314(d)(9) – 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

IN170.314(d)(9) – 1.02: Tester shall verify that the following elements have been recorded automatically for each disclosure:

- Date
- Time
- Patient Identification
- User Identification

TEST DATA

The Vendor shall supply the test data for this test procedure.

Vendor-supplied test data shall focus on meeting the basic capabilities required of EHR technology relative to the certification criterion rather than exercising the full breadth/depth of capability that installed EHR technology might be expected to support.

The test procedures require that the Tester enter the applicable test data into the EHR technology being evaluated for conformance. The intent is that the Tester fully controls the process of entering the test data in order to ensure that the data are correctly entered as specified in the test procedure. If a situation arises where it is impractical for a Tester to directly enter the test data, the Tester, at the Tester's discretion, may instruct the Vendor to enter the test data, so long as the Tester remains in full control of the testing process, directly observes the test data being entered by the Vendor, and validates that the test data are entered correctly as specified in the test procedure.

For Vendor-supplied test data, the Tester shall address the following:

- Vendor-supplied test data shall ensure that the 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
1.0	Released for public comment	September 7, 2012
1.1	Delivered for National Coordinator Approval	December 4, 2012
1.2	Posted Approved Test Procedure	December 14, 2012