

Test Procedure for §170.306 (i) Calculate and Submit Clinical Quality Measures

This document describes the draft test procedure for evaluating conformance of complete EHRs or EHR modules¹ 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 document² 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.

§170.306 (i) Calculate and submit clinical quality measures.

- (1) Calculate. Electronically calculate all of the clinical quality measures specified by CMS for eligible hospitals and critical access hospitals.
- (2) Submission. Enable a user to electronically submit calculated clinical quality measures in accordance with the standard and implementation specifications specified in §170.205(f).

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.

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 calculate and submit clinical quality measures certification criterion is discussed:

- "It is our understanding that the PQRI 2008 Registry XML specification is capable of serving as the "envelope" for aggregate, summary level data. Accordingly, we do not believe that, as some commenters suggested, an eligible hospital's familiarity with the PQRI program is relevant to the adoption of this standard for this specified purpose. Nor do we believe that a specific implementation of this standard is necessary for hospital settings as the standard's purpose and the type of data it will transmit to CMS will be the same – aggregate, summary level data."
- "Through recent discussions with CMS since the publication of the Interim Final Rule we have determined that the PQRI 2009 Registry XML specification, a more recent version of the standards we adopted in the Interim Final Rule is a suitable replacement for 2008 version, and accordingly, we have adopted the 2009 version in its place."
- "In light of the final approach CMS has taken with respect to clinical quality measures for meaningful use Stage 1, we have revised this certification to better align it with the Medicare and Medicaid EHR Incentive Programs final rule requirements. We also agree with those commenters that requested we explicitly focus the report of clinical quality measures certification criterion, and the certification criteria in general, on Federal requirements and have removed the reference to "or States" in this certification criterion."
- "To better align this certification criterion with the final approach to clinical quality measures in the Medicare and Medicaid EHR Incentive Programs final rule, we have determined that it is no longer sufficient to specify one general certification criterion for both Complete EHRs and EHR Modules designed for either an ambulatory or inpatient setting. Accordingly, the final rule in §170.304 and §170.306 will include a specific certification criterion for each setting."
- "Complete EHRs and EHR Modules designed for an inpatient setting will be required to be tested and certified as being compliant with all of the clinical quality measures specified by CMS (Section II(A)(3) of the Medicare and Medicaid EHR Incentive Programs final rule) for eligible hospitals. Again, we believe this revision provides greater clarity and reduces the potential burden for Complete EHR and EHR Module developers."

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 electronically calculate all of the clinical quality measures specified by CMS for eligible hospitals and critical access hospitals; and electronically submit calculated clinical quality measures in accordance with the standard and implementation specifications specified in §170.205(f).

This test procedure evaluates conformance to the Physician Quality Reporting Initiative (PQRI) standard and implementation specifications identified in the FR; however, the test procedure does not fully

evaluate the correctness of the implemented algorithms or calculation of the quality measures based on Vendor test data. An automated test tool to determine the correct calculation of measures is currently under development through an HHS/ONC effort.

The Vendor provides the test data for this test procedure.

This test procedure is organized into two sections:

- Calculate clinical quality measures – evaluates the capability to electronically calculate all of the clinical quality measures specified by CMS for eligible hospitals and critical access hospitals
 - The Tester examines the clinical quality measures specified by CMS in the EHR
 - The Tester validates that these clinical quality measures are electronically calculated by the EHR
 - The Tester will evaluate, to the extent possible given the Vendor-supplied data used in this Test Procedure, the calculations of the measures as described by the Vendor

- Submit calculated clinical quality measures – evaluates the capability to electronically submit calculated quality measures in accordance with the standard and implementation specifications
 - The Tester electronically submits the clinical quality measures calculated in the Calculate Clinical Quality Measures test
 - The Tester validates that the calculated clinical quality measures are submitted in accordance with the PQRI standard and implementation specifications
 - The tester will evaluate, to the extent possible given the Vendor-supplied data used in this Test Procedure, the calculations of the measures as described by the Vendor

REFERENCED STANDARDS

170.205 Content exchange standards and implementation specifications for exchanging electronic health information.	Regulatory Referenced Standard
<u>(f) Quality reporting. Standard.</u> The CMS Physician Quality Reporting Initiative (PQRI) 2009 Registry XML Specification (incorporated by reference in §170.299). <u>Implementation specifications.</u> Physician Quality Reporting Initiative Measure Specifications Manual for Claims and Registry (incorporated by reference in §170.299).	Centers for Medicare & Medicaid Services, (CMS), 42 CFR Parts 412, 413, 422, and 495 RIN 0938-AP78, Medicare and Medicaid Programs; Electronic Health Record Incentive Program, Final Rule, July 28, 2010. Sections II (A) (3): Reporting on Clinical Quality Measures Using EHR by EPs, Eligible Hospitals and CAHs, Table 10: Clinical Quality Measures for Submission by Eligible Hospitals and CAHs for Payment Year 2011-2012

NORMATIVE TEST PROCEDURES

Derived Test Requirements

DTR170.306.i – 1: Electronically calculate clinical quality measures

DTR170.306.i – 2: Electronically submit calculated clinical quality measures

DTR170.306.i – 1: Electronically calculate clinical quality measures

Required Vendor Information

- VE170.306.i – 1.01: Vendor shall provide the test data necessary to accomplish the test procedure
- VE170.306.i – 1.02: Vendor shall describe the calculations implemented in the EHR for the specified CMS clinical quality measures for this test
- VE170.306.i – 1.03: Vendor shall identify the EHR function(s) that are available to: 1) electronically calculate the CMS clinical quality measures 2) electronically submit calculated clinical quality measures

Required Test Procedure:

- TE170.306.i – 1.01: Using the EHR function(s) identified by the Vendor, the Tester shall electronically calculate the specified CMS clinical quality measures
- TE170.306.i – 1.02: Using the NIST-supplied Inspection Test Guide, the Tester shall verify that the clinical quality measures are electronically calculated

Inspection Test Guide

- IN170.306.i – 1.01: Tester shall verify that the specified CMS clinical quality measures in the table below are calculated as described by the Vendor in VE170.306.i – 1.02

The tester will evaluate, to the extent possible given the Vendor-supplied test data used in this test procedure, the calculations of the measures as described by the Vendor

Clinical Quality Measures for Submission by Eligible Hospitals and CAHs for Payment Year 2011-2012

Per Department of Health and Human Services, Centers for Medicare & Medicaid Services, 42 CFR Parts 412, 413, 422, and 495, CMS-0033-F, RIN 0938-AP78, Medicare and Medicaid Programs; Electronic Health Record Incentive Program, Final Rule, July 28, 2010.

Measure Number Identifier	Clinical Quality Measure Title and Description ³
Emergency Department (ED)–1 NQF 0495	Title: Emergency Department Throughput—admitted patients. Median time from ED arrival to ED departure for admitted patients Description: Median time from emergency department arrival to time of departure from the emergency room for patients admitted to the facility from the emergency department Measure Developer: CMS/Oklahoma Foundation for Medical Quality (OFMQC)
ED–2 NQF 0497	Title: Emergency Department Throughput—admitted patients. Admission decision time to ED departure time for admitted patients Description: Median time from admit decision time to time of departure from the emergency department of emergency department patients admitted to inpatient status Measure Developer: CMS/OFMQ
Stroke-2 NQF 0435	Title: Ischemic stroke—Discharge on anti-thrombotics Description: Ischemic stroke patients prescribed antithrombotic therapy at hospital discharge Measure Developer: The Joint Commission
Stroke-3 NQF 0436	Title: Ischemic stroke—Anticoagulation for A-fib/flutter Description: Ischemic stroke patients with atrial fibrillation/flutter who are prescribed anticoagulation therapy at hospital discharge. Measure Developer: The Joint Commission
Stroke-4 NQF 0437	Title: Ischemic stroke—Thrombolytic therapy for patients arriving within 2 hours of symptom onset Description: Acute ischemic stroke patients who arrive at this hospital within 2 hours of time last known well and for whom IV t-PA was initiated at this hospital within 3 hours of time last known well. Measure Developer: The Joint Commission
Stroke-5 NQF 0438	Title: Ischemic or hemorrhagic stroke—Antithrombotic therapy by day 2 Description: Ischemic stroke patients administered antithrombotic therapy by the end of hospital day 2. Measure Developer: The Joint Commission
Stroke-6 NQF 0439	Title: Ischemic stroke—Discharge on statins Description: Ischemic stroke patients with LDL > 100 mg/dL, or LDL not measured, or, who were on a lipid-lowering medication prior to hospital arrival are prescribed statin medication at hospital discharge. Measure Developer: The Joint Commission
Stroke-8 NQF 0440	Title: Ischemic or hemorrhagic stroke—Stroke education Description: Ischemic or hemorrhagic stroke patients or their caregivers who were given educational materials during the hospital stay addressing all of the following: activation of emergency medical system, need for follow-up after discharge, medications prescribed at discharge, risk factors for stroke, and warning signs and symptoms of stroke. Measure Developer: The Joint Commission
Stroke-10 NQF 0441	Title: Ischemic or hemorrhagic stroke—Rehabilitation assessment Description: Ischemic or hemorrhagic stroke patients who were assessed for rehabilitation services. Measure Developer: The Joint Commission

³ The detailed electronic specifications of the clinical quality measures for EPs, eligible hospitals, and CAHs are displayed on the CMS website at http://www.cms.gov/QualityMeasures/03_ElectronicSpecifications.asp#TopOfPage.

Measure Number Identifier	Clinical Quality Measure Title and Description ³
Venous Thromboembolism (VTE)–1 NQF 0371	Title: VTE prophylaxis within 24 hours of arrival Description: This measure assesses the number of patients who received VTE prophylaxis or have documentation why no VTE prophylaxis was given the day of or the day after hospital admission or surgery end date for surgeries that start the day of or the day after hospital admission. Measure Developer: The Joint Commission
VTE–2 NQF 0372	Title: ICU VTE prophylaxis Description: This measure assesses the number of patients who received VTE prophylaxis or have documentation why no VTE prophylaxis was given the day of or the day after the initial admission (or transfer) to the Intensive Care Unit (ICU) or surgery end date for surgeries that start the day of or the day after ICU admission (or transfer). Measure Developer: The Joint Commission
VTE–3 NQF 0373	Title: Anticoagulation overlap therapy Description: This measure assesses the number of patients diagnosed with confirmed VTE who received an overlap of parenteral (intravenous [IV] or subcutaneous [subcu]) anticoagulation and warfarin therapy. For patients who received less than five days of overlap therapy, they must be discharged on both medications. Overlap therapy must be administered for at least five days with an international normalized ratio (INR) ≥ 2 prior to discontinuation of the parenteral anticoagulation therapy or the patient must be discharged on both medications. Measure Developer: The Joint Commission
VTE–4 NQF 0374	Title: Platelet monitoring on unfractionated heparin Description: This measure assesses the number of patients diagnosed with confirmed VTE who received intravenous (IV) UFH therapy dosages AND had their platelet counts monitored using defined parameters such as a nomogram or protocol. Measure Developer: The Joint Commission
VTE–5 NQF 0375	Title: VTE discharge instructions Description: This measure assesses the number of patients diagnosed with confirmed VTE that are discharged to home, to home with home health, home hospice or discharged/transferred to court/law enforcement on warfarin with written discharge instructions that address all four criteria: compliance issues, dietary advice, follow-up monitoring, and information about the potential for adverse drug reactions/interactions. Measure Developer: The Joint Commission
VTE–6 NQF 0376	Title: Incidence of potentially preventable VTE Description: This measure assesses the number of patients diagnosed with confirmed VTE during hospitalization (not present on arrival) who did not receive VTE prophylaxis between hospital admission and the day before the VTE diagnostic testing order date. Measure Developer: The Joint Commission

DTR170.306.i – 2: Electronically submit calculated clinical quality measures

Required Vendor Information

- As defined in DTR170.306.i – 1, no additional information is required

Required Test Procedure:

TE170.306.i – 2.01: Using the EHR function(s) identified by the Vendor, the Tester shall electronically submit the specified CMS clinical quality measures from the DTR170.306.i – 1: Electronically calculate clinical quality measures test

TE170.306.i – 2.02: Using the NIST-supplied Inspection Test Guide, the Tester shall verify that the clinical quality measures are submitted in conformance with the PQRI standard and implementation specifications referenced in the FR

Inspection Test Guide

IN170.306.i – 2.01: Tester shall visually inspect the submitted PQRI XML document “envelop” for the specified CMS clinical quality measures in the table below and verify that, at a minimum, the following information is present and the data tags are appropriate:

- Submission-period-from-date
- Submission-period-to-date
- Submission method
- Measure group
- Provider
- National Provider Identifier
- Clinical quality measure
- Measure number identifier
- Eligible instances (reporting denominator)
- Meets performance (performance numerator)
- Performance exclusion instances
- Performance not met instances
- Reporting rate
- Performance rate

Clinical Quality Measures for Submission by Eligible Hospitals and CAHs for Payment Year 2011-2012

Per Department of Health and Human Services, Centers for Medicare & Medicaid Services, 42 CFR Parts 412, 413, 422, and 495, CMS-0033-F, RIN 0938-AP78, Medicare and Medicaid Programs; Electronic Health Record Incentive Program, Final Rule, July 28, 2010.

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VTE-4 NQF 0374	<p>Title: Platelet monitoring on unfractionated heparin</p> <p>Description: This measure assesses the number of patients diagnosed with confirmed VTE who received intravenous (IV) UFH therapy dosages AND had their platelet counts monitored using defined parameters such as a nomogram or protocol.</p> <p>Measure Developer: The Joint Commission</p>
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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

An automated test tool to determine the correct calculation of measures is currently under development through an HHS/ONC effort.

Document History

Version Number	Description of Change	Date Published
0.2	Original draft version	April 9, 2010
1.0	Updated to reflect Final Rule	July 21, 2010
1.0	Updated to remove "Pending" from header	August 13, 2010