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Test Procedure for §170.314(a)(19) Optional – computerized provider order entry – laboratory

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 2014 Edition Release 2 Electronic Health Record (EHR) Certification Criteria and the ONC HIT Certification Program; Regulatory Flexibilities, Improvements, and Enhanced Health Information Exchange Final Rule [September 11, 2014]. 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.

Questions or concerns regarding the ONC HIT Certification Program should be submitted at: http://jira.oncprojecttracking.org/browse/CERT

CERTIFICATION CRITERIA

Refer to §170.314 (a)(19) for the certification criteria.

Per Section III.A.2 of the preamble of the 2014 Edition, Release 2 Electronic Health Record (EHR) Certification Criteria and the ONC HIT Certification Program; Regulatory Flexibilities, Improvements, and Enhanced Health Information Exchange Final Rule (September 11, 2014), this certification criterion is adopted as part of the 2014 Release 2 Edition test method and is classified as "optional".

2014 EDITION RELEASE 2 PREAMBLE LANGUAGE

Per Section III.A.2 of the preamble of the 2014 Edition, Release 2 Electronic Health Record (EHR) Certification Criteria and the ONC HIT Certification Program; Regulatory Flexibilities, Improvements, and Enhanced Health Information Exchange Final Rule (September 11, 2014). The optional certification criteria include the splitting of the "computerized provider order entry" (CPOE) criterion into three certification criteria based on capabilities (medications, laboratory, and diagnostic imaging).

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.

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

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This test evaluates the capability for EHR technology to enable a user to electronically record, change, and access the order type: laboratory.

The test procedure is not prescriptive about the method used to change an order. For example, changing an order does not require changing an existing instance of an order. Change may be accomplished through discontinuing/canceling an existing order and entering a new order.

ONC supplies part of the test data and the Vendor supplies part of the test data for this test procedure. This test procedure is organized into three sections:

- Record – evaluates the capability to electronically enter orders for laboratory within the EHR system
    - o The Tester enters the ONC-supplied test data orders for laboratory
    - o The Tester verifies that the orders are recorded in the EHR

- Change – evaluates the capability for a user to electronically change entered orders for laboratory in the EHR
    - o The Tester displays the entered orders for laboratory
    - o Tester changes the laboratory orders
    - o The Tester verifies that the changed orders are accurate and complete

- Access – evaluates the capability to access and display the orders that have been previously entered into the EHR
    - o The Tester displays the orders for laboratory entered   during the test
    - o The Tester verifies that the displayed order data are accurate and complete

For EHR technology **targeted to the ambulatory setting**, the following derived test requirements apply:
- o DTR170.314(a)(19) – 1: Electronically Record Orders in an Ambulatory Setting
- o DTR170.314(a)(19) – 2: Electronically Change Orders in an Ambulatory Setting
- o DTR170.314(a)(19) – 3: Electronically Access Orders in an Ambulatory Setting

For EHR technology **targeted to the inpatient setting**, the following derived test requirements apply:
- o DTR170.314(a)(19) – 4: Electronically Record Orders in an Inpatient Setting
- o DTR170.314(a)(19) – 5: Electronically Change Orders in an Inpatient Setting
- o DTR170.314(a)(19) – 6: Electronically Access Orders in an Inpatient Setting

For EHR technology **targeted to both settings**, the following derived test requirements apply:
- o DTR170.314(a)(19) – 1: Electronically Record Orders in an Ambulatory Setting
- o DTR170.314(a)(19) – 2: Electronically Change Orders in an Ambulatory Setting
- o DTR170.314(a)(19) – 3: Electronically Access Orders in an Ambulatory Setting

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- o DTR170.314(a)(19) – 4: Electronically Record Orders in an Inpatient Setting
- o DTR170.314(a)(19) – 5: Electronically Change Orders in an Inpatient Setting
- o DTR170.314(a)(19) – 6: Electronically Access Orders in an Inpatient Setting

REFERENCED STANDARDS

None

NORMATIVE TEST PROCEDURES – AMBULATORY SETTING

Derived Test Requirements

DTR170.314(a)(19) – 1: Electronically Record Orders in an Ambulatory Setting

DTR170.314(a)(19) – 2: Electronically Change Orders in an Ambulatory Setting

DTR170.314(a)(19) – 3: Electronically Access Orders in an Ambulatory Setting

DTR170.314(a)(19) – 1: Electronically Record Orders in an Ambulatory Setting

Required Vendor Information

VE170.314(a)(19) – 1.01: Vendor shall identify a patient with an existing record in the EHR to be used for this test

VE170.314(a)(19) – 1.02: Vendor shall identify the EHR function(s) that are available to: 1) select the patient, 2) enter orders for laboratory 3) change orders for laboratory and 4) access orders for laboratory in an ambulatory setting

Required Test Procedure

TE170.314(a)(19) – 1.01: Tester shall select order test data from one ONC-supplied test data set in TD170.314(a)(19) – 1

TE170.314(a)(19) – 1.02: Using the EHR function(s) identified by the Vendor, the Tester shall select the patient's existing record and enter orders from the selected test data set in TD170.314(a)(19) – 1

TE170.314(a)(19) – 1.03: Using the Inspection Test Guide (below), the Tester shall verify that the orders have been entered correctly and without omission

Inspection Test Guide

IN170.314(a)(19) – 1.01: Using the data in the selected ONC-supplied test data set in TD170.314(a)(19) – 1, Tester shall verify that the order test data are entered correctly and without omission

IN170.314(a)(19) – 1.02: Tester shall verify that the order data are recorded in the patient's record for data elements listed in TE170.314(a)(19) – 1.02

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DTR170.314(a)(19) – 2: Electronically Change Orders in an Ambulatory Setting

Required Vendor Information

- As defined in DTR170.314(a)(19) – 1, no additional information is required

Required Test Procedure

TE170.314(a)(19) – 2.01: Tester shall select order test data from one ONC-supplied test data set in TD170.314(a)(19) – 2 that corresponds to the data set selected for DTR170.314(a)(19) – 1: Electronically Record Orders in an Ambulatory Setting

TE170.314(a)(19) – 2.02: Using the EHR function(s) identified by the Vendor, the Tester shall select the patient's existing record, shall display the order data entered during the DTR170.314(a)(19) – 1: Electronically Record Orders in an Ambulatory Setting test, and shall change the previously entered orders for the data elements listed in TE170.314(a)(19) – 1.02

TE170.314(a)(19)– 2.03: Using the Inspection Test Guide (below), the Tester shall verify that the orders that were entered in TE170.314(a)(19) – 2.02 have been entered correctly and without omission

Inspection Test Guide

IN170.314(a)(19) – 2.01: Using the data in the selected ONC-supplied test data set in TD170.314(a)(19) – 2, Tester shall verify that the laboratory order data entered during the DTR170.314(a)(19) – 1: Electronically Record Orders in an Ambulatory Setting test are accessed and changed correctly and without omission

IN170.314(a)(19) – 2.02: Tester shall verify that the changed orders are recorded in the patient record correctly, including the data elements listed in TE170.314(a)(19) – 1.02

DTR170.314(a)(19) – 3: Electronically Access Orders in an Ambulatory Setting

Required Vendor Information

- As defined in DTR170.314(a)(19) – 1, no additional information is required

Required Test Procedure

TE170.314(a)(19) – 3.01: Using the EHR function(s) identified by the Vendor, the Tester shall select the patient's existing record and display the orders the Tester entered during the DTR170.314(a)(19) – 1: Electronically Record Orders in an Ambulatory Setting test and changed during the

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DTR170.314(a)(19) – 2: Electronically Change   Orders in an Ambulatory
Setting test for the data elements listed in TE170.314(a)(19) – 1.02

TE170.314(a)(19) – 3.02: Using the Inspection Test Guide (below), the Tester shall verify that
the order data display correctly and without omission

Inspection Test Guide

IN170.314(a)(19) – 3.01: Using the data in the ONC-supplied test data set in TD170.314(a)(19) –
3 that corresponds to the data set selected for DTR170.314(a)(19) – 1:
Electronically Record Orders in an Ambulatory Setting, Tester shall
verify that the order data entered during the DTR170.314(a)(19) – 1:
Electronically Record Orders in an Ambulatory Setting test and changed
during the DTR170.314(a)(19) – 2: Electronically Change Orders in an
Ambulatory Setting test display correctly and without omission, including
the data elements listed in TE170.314(a)(19) – 1.02

NORMATIVE TEST PROCEDURES – INPATIENT SETTING

Derived Test Requirements

DTR170.314(a)(19) – 4: Electronically Record Orders in an Inpatient Setting

DTR170.314(a)(19) – 5: Electronically Change Orders in an Inpatient Setting

DTR170.314(a)(19) – 6: Electronically Access Orders in an Inpatient Setting

DTR170.314(a)(19) – 4: Electronically Record Orders in an Inpatient Setting

Required Vendor Information

VE170.314(a)(19) – 4.01: Vendor shall identify a patient with an existing record in the EHR to be
used for this test

VE170.314(a)(19) – 4.02: Vendor shall identify the EHR function(s) that are available to: 1) select
the patient, 2) enter orders for laboratory, 3) change orders for laboratory,
and 4) access orders for laboratory in an inpatient setting

Required Test Procedure

TE170.314(a)(19) – 4.01: Tester shall select order test data from one ONC-supplied test data set
in TD170.314(a)(19) – 4

TE170.314(a)(19) – 4.02: Using the EHR function(s) identified by the Vendor, the Tester shall
select the patient's existing record and enter orders from the selected
test data set in TD170.314(a)(19) – 4

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TE170.314(a)(19) – 4.03: Using the Inspection Test Guide (below), the Tester shall verify that the orders have been entered correctly and without omission

Inspection Test Guide

IN170.314(a)(19) – 4.01: Using the data in the selected ONC-supplied test data set in TD170.314(a)(19) – 4, Tester shall verify that the order test data are entered correctly and without omission

IN170.314(a)(19) – 4.02: Tester shall verify that the order data are recorded in the patient's record for the data elements listed in TE170.314(a)(19) – 4.02

DTR170.314(a)(19) – 5: Electronically Change Orders in an Inpatient Setting

Required Vendor Information

- As defined in DTR170.314(a)(19) – 4, no additional information is required

Required Test Procedure

TE170.314(a)(19) – 5.01: Tester shall select order test data from one ONC-supplied test data set in TD170.314(a)(19) – 5 that corresponds to the data set selected for DTR170.314(a)(19) – 4: Electronically Record Orders in an Inpatient Setting

TE170.314(a)(19) – 5.02: Using the EHR function(s) identified by the Vendor, the Tester shall select the patient's existing record, shall display the order data entered during the DTR170.314(a)(19) – 4: Electronically Record Orders in an Inpatient Setting test, and shall change the previously entered orders for the data elements listed in TE170.314(a)(19) – 4.02

TE170.314(a)(19)– 5.03: Using the Inspection Test Guide (below), the Tester shall verify that the orders that were entered in TE170.314(a)(19) – 5.02 have been entered correctly and without omission

Inspection Test Guide

IN170.314(a)(19) – 5.01: Using the data in the selected ONC-supplied test data set in TD170.314(a)(19)– 5, Tester shall verify that the laboratory order data entered during the DTR170.314(a)(19) – 4: Electronically Record Orders in an Inpatient Setting test are accessed and changed correctly and without omission

IN170.314(a)(19) – 5.02: Tester shall verify that the changed orders are recorded in the patient record correctly, including the data elements listed in TE170.314(a)(19) – 4.02

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DTR170.314(a)(19) – 6: Electronically Access Orders in an Inpatient Setting

Required Vendor Information

- As defined in DTR170.314(a)(19) – 4, no additional information is required

Required Test Procedure

TE170.314(a)(19) – 6.01: Using the EHR function(s) identified by the Vendor, the Tester shall select the patient's existing record and display the orders the Tester entered during the DTR170.314(a)(19) – 4: Electronically Record Orders in an Inpatient Setting test and changed during the DTR170.314(a)(19) – 5: Electronically Change Orders in an Inpatient Setting test for the data elements listed in TE170.314(a)(19) – 4.02

TE170.314(a)(19) – 6.02: Using the Inspection Test Guide (below), the Tester shall verify that the order data display correctly and without omission

Inspection Test Guide

IN170.314(a)(19) – 6.01: Using the data in the ONC-supplied test data set in TD170.314(a)(19) – 6 that corresponds to the data set selected for DTR170.314(a)(19) – 4: Electronically Record Orders in an Inpatient Setting, Tester shall verify that the order data entered during the DTR170.314(a)(19) – 4: Electronically Record Orders in an Inpatient Setting test and changed during the DTR170.314(a)(19) – 5: Electronically Change Orders in an Inpatient Setting test display correctly and without omission, including the data elements listed in TE170.314(a)(19) – 4.02

TEST DATA

ONC- and Vendor-supplied test data are provided with the test procedure to ensure that the applicable requirements identified in the criteria can be adequately evaluated for conformance, as well as to provide consistency in the testing process across multiple National Voluntary Laboratory Accreditation Program (NVLAP)-Accredited Testing Labs (ATLs). The provided test data focus on evaluating the basic capabilities of required EHR technology, rather than exercising the full breadth/depth of capability that installed EHR technology might be expected to support. The test data are formatted for readability of use within the testing process. The format is not prescribing a particular end-user view or rendering. No additional requirements should be drawn from the format.

The Tester shall use and apply the provided test data during the test, without exception, unless one of the following conditions exists:

- The test procedure requires or permits the use of vendor-supplied test data.
- The Tester determines that the Vendor product is sufficiently specialized that the

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provided test data needs to be modified in order to conduct an adequate test. Having made the determination that some modification to the provided test data is necessary, the Tester shall record the modifications made as part of the test documentation.

• The Tester determines that changes to the test data will improve the efficiency of the testing   process; primarily through using consistent demographic data throughout the testing workflow. The Tester shall ensure that the applicable requirements identified in the criterion   can be adequately evaluated for conformance and that the test data provides a comparable level of robustness. Having made the determination that some modification to the provided   test data is necessary, the Tester shall record the modifications made as part of the test   documentation.

Any departure from the provided test data shall strictly 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.

For additional information regarding the provided test data for use in this test procedure:

• Test Data for §170.314(a)(19) Computerized provider order entry available at http://www.healthit.gov/certification (navigation: 2014 Edition Test Method).

CONFORMANCE TEST TOOLS

None

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Document History

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1.0	Released for public comment	October 2014