2014 Edition
Test Procedure for §170.314.a.16 Electronic medication administration record –
inpatient setting only
For Public Comment ■ September 21, 2012

The Office of the National Coordinator for
Health Information Technology

Test Procedure for §170.314(a)(16) Electronic medication administration record – inpatient setting only

This document describes the test procedure for evaluating conformance of Complete EHRs or EHR modules 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 [available when final]. 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. Testing of EHR technology in the Permanent Certification Program, henceforth referred to as the ONC HIT Certification Program[2], is carried out by National Voluntary Laboratory Accreditation Program-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 CRITERIA

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(a)(16) <u>Inpatient setting only—electronic medication administration record</u>.
(i) In combination with an assistive technology that provides automated information on the "rights" specified in paragraphs (a)(16)(i)(A) through (E) of this section, enable a user to electronically verify the following before administering medication(s):

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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.

[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

2014 Edition
Test Procedure for §170.314.a.16 Electronic medication administration record –
inpatient setting only
For Public Comment ■ September 21, 2012

The Office of the National Coordinator for
Health Information Technology

(A) Right patient. The patient to whom the medication is to be administered matches the medication to be administered.

(B) Right medication. The medication to be administered matches the medication ordered for the patient.

(C) Right dose. The dose of the medication to be administered matches the dose of the medication ordered for the patient.

(D) Right route. The route of medication delivery matches the route specified in the medication order.

(E) Right time. The time that the medication was ordered to be administered compared to the current time.

(ii) Right documentation. Electronically record the time and date in accordance with the standard specified in § 170.210(g), and user identification when a medication is administered.

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 this certification criterion is classified as new from the 2011 Edition. This certification criterion meets at least one of the factors of new certification criteria: (1) the certification criterion only specifies capabilities that have never been included in previously adopted certification criteria, or (2) the certification criterion was previously adopted as "mandatory" for a particular setting and subsequently adopted as "mandatory" or "optional" for a different setting.

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 where the electronic medication administration record certification criterion is discussed:

- "We have purposefully framed this certification criterion to leave open a range of different technologies that could be used to demonstrate compliance with the certification criterion. We do not intend to single out only one particular technology that would meet this certification criterion. We interpret "assistive technology" to be a technological solution that when paired with EHR technology automates the comparative aspects of the five rights that a user would otherwise have to manually complete."

- "…clarification on whether "electronically" recording the time, date, and user ID at the time of administration is a function automatically performed by the system, or whether allowing a user to manually enter this data is sufficient…We intend for this information to be automatically and simultaneously recorded with the use of the assistive technology. A manual entry feature for emergency/unanticipated circumstances is not prohibited by this certification criterion from existing, but would not alone allow for EHR technology to meet this certification criterion."

- "…we interpret "electronically verify" in the certification criterion to mean that upon the use of an assistive technology a user would be able to review and compare within the EHR technology the

2014 Edition
Test Procedure for §170.314.a.16 Electronic medication administration record –
inpatient setting only
For Public Comment ■ September 21, 2012

The Office of the National Coordinator for
Health Information Technology

five rights information associated with the medication to be administered. By being able to verify this information, the user would be able to assess whether the five rights are correct and subsequently administer the medication with appropriate documentation."

- "…"electronically verify" does not require EHR technology to provide some type of explicit notification to a user if all of the five rights are correct. However, if one or more are incorrect, the EHR technology must provide some indication to a user which "right(s)" are incorrect/not within compliant parameters."

- "…there are other steps within the medication administration workflow for which user interaction with, and entries into, EHR technology may be necessary. This certification criterion is not meant to preclude those other steps nor are they within the current scope of this certification criterion.

- "A commenter requested clarification on how automation can determine the "right route."…The automated aspect of this certification criterion is the provision of information associated with the medication to be administered; in other words, that the dosage form of the medication is appropriate to the ordered route. Thus, when an assistive technology is used, the information about the route of medication delivery would need to be automatically available for a user to verify."

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 Modules to enable a user to electronically verify the 5 Rights of medication administration via assistive technology prior to administering a medication to a patient, and to record the Right Documentation of medication administration (including the time and date the medication was administered and the administering user's identification). The test also verifies that the date and time of each medication administration action are electronically, automatically, and simultaneously recorded utilizing a system clock that has been synchronized following (RFC[3] 1305) Network Time Protocol, or (RFC 5905) Network Time Protocol Version 4.

Due to the physical realities associated with testing for this criterion (i.e., use of an assistive technology and associated materials that must be handled during the test), the test procedure steps are designed to allow the Tester to observe from a remote location while the Vendor demonstrates use of their assistive technology in combination with their EHR system.

This test procedure is not prescriptive about the method used to capture the user's identification. For example, the user's identification may be captured from the user's ID/password combination when the

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[3] Request for Comments

2014 Edition
Test Procedure for §170.314.a.16 Electronic medication administration record –
inpatient setting only
For Public Comment ■ September 21, 2012

user initially logs on to the EHR; from the user's ID/password combination when the user enters these data during the medication administration process; and by scanning a user's ID bar code.

This test procedure includes a Network Time Protocol (NTP) test to verify synchronization of the EHR and the system clock to the named standards, (RFC 1305) Network Time Protocol, or (RFC 5905) Network Time Protocol Version 4.

ONC provides the test data for this test procedure.

This test procedure is organized into two sections:

- Verify – evaluates the capability of the EHR technology to electronically verify the "5 rights" of medication administration (right patient, right medication, right dose, right route, right time) using automated assistive technology
  - o Using the ONC-supplied test data as instructed by the Tester, the Vendor creates two existing patient records in the EHR technology (one to be used for showing the verification of 5 Rights when all of the Rights are correct, and one to be used for showing the verification of 5 Rights when some or all of the Rights are incorrect), and generates the materials needed by the assistive technology for positive identification of the test patients (e.g., patient ID bar codes)
  - o Using the ONC-supplied test data as instructed by the Tester, the Vendor inputs medication orders into each test patient's record
  - o Using the Vendor-identified EHR function(s), the EHR's assistive technology and associated materials, one of the test patients, and the provided test data, the Tester verifies that all of the 5 Rights are correct, i.e., the right medications are being administered to the right patient, with the right doses, via the right routes, and at the right times based on the medication orders entered into the EHR for that test patient
    OR The Tester observes, via remote capability, the EHR Vendor using the Vendor-identified EHR function(s), the EHR's assistive technology and associated materials, one of the test patients, and the ONC-supplied test data to verify that all of the 5 Rights are correct, i.e., the right medications are being administered to the right patient, with the right doses, via the right routes, and at the right times based on the medication orders entered into the EHR for that test patient
  - o Using the Vendor-identified EHR function(s), the EHR's assistive technology and associated materials, a second test patient, and the ONC-supplied test data, the Tester verifies that the EHR technology alerts the user about a "wrong patient"
    OR The Tester observes, via remote capability, the EHR Vendor using the Vendor-identified EHR function(s), the EHR's assistive technology and associated materials, a second test patient, and the ONC-supplied test data, to verify that the EHR technology alerts the user about a "wrong patient"
  - o Using the Vendor-identified EHR function(s), the EHR's assistive technology and associated materials, the second test patient correctly identified by the assistive technology, and the ONC-

2014 Edition
Test Procedure for §170.314.a.16 Electronic medication administration record –
inpatient setting only
For Public Comment ■ September 21, 2012

The Office of the National Coordinator for
Health Information Technology

supplied test data, the Tester verifies that the EHR technology alerts the user about a "wrong medication", a "wrong dose", a "wrong route", and a "wrong time" based on the medication orders entered into the EHR for that test patient

OR The Tester observes, via remote capability, the EHR Vendor using the Vendor-identified EHR function(s), the EHR's assistive technology and associated materials, the second test patient correctly identified by the assistive technology, and ONC-supplied test data to verify that the EHR technology alerts the user about a "wrong medication", a "wrong dose", a "wrong route", and a "wrong time" based on the medication orders entered into the EHR for that test patient

- o The Tester verifies that the EHR technology enables the user to
  - Review and compare the 5 Rights information associated with the medications being administered
  - Assess whether the 5 Rights are correct or if any of the 5 Rights are incorrect

- Record – evaluates the capability for a user to electronically, automatically, and simultaneously record in the EHR technology the right documentation when each medication is administered, including the date, time, and user identification
  - o For the medication administrations performed/completed in the "Verify" step
    - Using the Vendor-identified EHR technology function(s), the Tester electronically, automatically, and simultaneously records the date, time, and user identification data for each administered medication, with the date/time determined automatically via a system clock that is synchronized per the named synchronized clocks standard
      OR
    - The Tester observes, via remote capability, the EHR Vendor using the Vendor-identified EHR function(s) to electronically, automatically, and simultaneously record the date, time, and user identification data for each administered medication, with the date/time determined automatically via a system clock that is synchronized per the named synchronized clocks standard
  - o The Tester verifies that the EHR technology enables the user to electronically, automatically, and simultaneously record the date, time and user identification for each administered medication with the use of the assistive technology, and that the correct dates, times, and user identification are captured and stored in the patient's record

2014 Edition
Test Procedure for §170.314.a.16 Electronic medication administration record – inpatient setting only
For Public Comment ■ September 21, 2012

The Office of the National Coordinator for
Health Information Technology

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 standard to protect electronic health information created, maintained, and exchanged:	
(g) Synchronized clocks. The date and time recorded utilize a system clock that has been synchronized following (RFC 1305) Network Time Protocol, (incorporated by reference in §170.299) or (RFC 5905) Network Time Protocol Version 4, (incorporated by reference in §170.299).	

NORMATIVE TEST PROCEDURES

Network Time Protocol (NTP) Test

The test steps below must be performed by the Vendor and the results validated by the Tester prior to beginning the test steps in the Derived Test Requirements.

NTP170.314.a.16 – 1.01: The Vendor shall choose a time server from the list below, used by the NIST Internet Time Service (ITS), and shall add it to their NTP software configuration

Note: All users should ensure that their software NEVER queries a server more frequently than once every 4 seconds. Systems that exceed this rate will be refused service. In extreme cases, systems that exceed this limit may be considered as attempting a denial-of-service attack.

Name	IP Address	Location
nist1-ny.ustiming.org	64.90.182.55	New York City, NY
nist1-nj.ustiming.org	96.47.67.105	Bridgewater, NJ
nist1-pa.ustiming.org	206.246.122.250	Hatfield, PA
time-a.nist.gov	129.6.15.28	NIST, Gaithersburg, Maryland
time-b.nist.gov	129.6.15.29	NIST, Gaithersburg, Maryland
nist1.aol-va.symmetricom.com	64.236.96.53	Reston, Virginia
nist1.columbiacountyga.gov	216.119.63.113	Columbia County, Georgia
nist1-atl.ustiming.org	64.250.177.145	Atlanta, Georgia
nist1-chi.ustiming.org	216.171.120.36	Chicago, Illinois
nist-chicago (No DNS)	38.106.177.10	Chicago, Illinois

2014 Edition
Test Procedure for §170.314.a.16 Electronic medication administration record – inpatient setting only
For Public Comment ■ September 21, 2012

The Office of the National Coordinator for
Health Information Technology

nist.time.nosc.us	96.226.123.117	Carrollton, Texas
nist.expertsmi.com	50.77.217.185	Monroe, Michigan
nist.netservicesgroup.com	64.113.32.5	Southfield, Michigan
nisttime.carsoncity.k12.mi.us	66.219.116.140	Carson City, Michigan
nist1-lnk.binary.net	216.229.0.179	Lincoln, Nebraska
wwv.nist.gov	24.56.178.140	WWV, Fort Collins, Colorado
time-a.timefreq.bldrdoc.gov	132.163.4.101	NIST, Boulder, Colorado
time-b.timefreq.bldrdoc.gov	132.163.4.102	NIST, Boulder, Colorado
time-c.timefreq.bldrdoc.gov	132.163.4.103	NIST, Boulder, Colorado
time.nist.gov	global address for all servers	Multiple locations
utcnist.colorado.edu	128.138.140.44	University of Colorado, Boulder
utcnist2.colorado.edu	128.138.141.172	University of Colorado, Boulder
ntp-nist.ldsbc.edu	198.60.73.8	LDSBC, Salt Lake City, Utah
nist1-lv.ustiming.org	64.250.229.100	Las Vegas, Nevada
time-nw.nist.gov	131.107.13.100	Microsoft, Redmond, Washington
nist-time-server.eoni.com	216.228.192.69	La Grande, Oregon
nist1.aol-ca.symmetricom.com	207.200.81.113	Mountain View, California
nist1.symmetricom.com	69.25.96.13	San Jose, California
nist1-sj.ustiming.org	216.171.124.36	San Jose, California
nist1-la.ustiming.org	64.147.116.229	Los Angeles, California

NTP170.314.a.16 – 1.02: After configuring NTP, the Vendor shall wait 15 minutes to ensure synchronization occurs

NTP170.314.a.16 – 1.03: Using the NTP logs, the Vendor and Tester shall verify that the system time is within one-second accuracy of the NIST time sever chosen in NTP170.314.a.16 – 1.01

NTP170.314.a.16 – 1.04: The Vendor shall construct or use an existing display in the EHR system that shows the time from the system clock and the EHR time for comparison (these times should be synchronized to within one second)

2014 Edition
Test Procedure for §170.314.a.16 Electronic medication administration record –
inpatient setting only
For Public Comment ■ September 21, 2012

The Office of the National Coordinator for
Health Information Technology

NTP170.314.a.16 – 1.05: The Tester shall verify, via the NTP logs, that the system time is synchronized to the NIST time server to within one second; and then the Tester shall verify, via the EHR display, that the EHR time is synchronized to the system time to within one second

Derived Test Requirements

DTR170.314.a.16 – 1: Electronically Verify the 5 Rights of Medication Administration

DTR170.314.a.16 – 2: Electronically Record the Right Documentation of Medication Administration

DTR170.314.a.16 – 1: Electronically Verify the 5 Rights of Medication Administration

Required Vendor Information

VE170.314.a.16 – 1.01: Using the ONC-supplied test data as instructed by the Tester, the Vendor shall create two existing test patient records in the EHR, and shall generate the materials needed by the assistive technology for identification of these patients (e.g., patient ID bar codes)

VE170.314.a.16 – 1.02: Using the ONC-supplied test data as instructed by the Tester, the Vendor shall input the medication order information into the records of the test patients, and shall provide the materials needed by the assistive technology for identification of the medications (e.g., unit dose bar codes)

VE170.314.a.16 – 1.03: The Vendor shall identify a user (and this user's identification information that is captured and stored in the EHR) with the authorization to use the EHR's electronic medication administration record (eMAR) and medication administration assistive technology to record the administration of medications in a patient's record

VE170.314.a.16 – 1.04: The Vendor shall provide assistive technology required to 1) electronically verify the right patient (e.g., bar code reader and a patient identification bar codes), 2) electronically verify the right medication, right dose, right route, and right time (e.g., bar code reader and medication identification bar codes) for the medications to be administered using assistive technology, 3) electronically identify the user who is administering the medications

VE170.314.a.16 – 1.05: The Vendor shall identify the EHR function(s) that are available to 1) select a test patient, 2) access the eMAR, 3) electronically verify the right patient, right medication, right dose, right route, and right time for the medications administered using assistive technology, and 4) record the date, time, and user identification information for the medications administered

VE170.314.a.16 – 1.06: The Vendor shall identify the protocol used for synchronizing the EHR system clock (i.e., (RFC 1305) Network Time Protocol, or (RFC 5905) Network Time Protocol Version 4)

2014 Edition
Test Procedure for §170.314.a.16 Electronic medication administration record –
inpatient setting only
For Public Comment ■ September 21, 2012

The Office of the National Coordinator for
Health Information Technology

VE170.314.a.16 – 1.07: The Vendor shall identify the remote video or other capability to be used for this test if use of the assistive technology is to be observed remotely by the Tester

Required Test Procedure:

TE170.314.a.16 – 1.01: The Tester shall select one of the data sets from the ONC-supplied test data in TD170.314.a.16 **–** 1: Electronically Verify the 5 Rights of Medication Administration, and shall provide the Vendor with the data needed for VE170.314.a.16 – 1.01 and VE170.314.a.16 – 1.02

TE170.314.a.16 – 1.02: Using the test data selected in TE170.314.a.16 – 1.01, the Tester shall observe the Vendor creating the test patient records and inputting the medication orders into those test patient records

TE170.314.a.16 – 1.03: Using the Vendor-identified EHR function(s)/assistive technology and associated materials (e.g., bar coded items), the test data selected in TE170.314.a.16 – 1.01, and the first test patient, the Tester shall sign on as a Vendor-identified user with medication administration authorization and shall access (or shall observe, via remote capability, the EHR Vendor signing on and accessing) the eMAR of the test patient

TE170.314.a.16 – 1.04: The Tester shall use (or shall observe, via remote capability, the EHR Vendor using) the EHR assistive technology as described by the Vendor to
- Verify that the patient is the right patient
- Verify for each of the medications ordered for this patient
  o That the medication being administered is the right medication based on the medication order that was input into the EHR
  o That the dose being administered matches the dose information in the medication order that was input into the EHR
  o That the route of the medication being administered matches the route information in the medication order that was input into the EHR
  o That the current time matches the time indicated for the medication being administered in the medication order that was input into the EHR

TE170.314.a.16 – 1.05: Using the Inspection Test Guide, the Tester shall verify that the patient and medications are verified correctly and accurately by the EHR medication administration assistive technology

TE170.314.a.16 – 1.06: For each of the medications administered, the Tester shall note the date and time (utilizing a system clock that has been synchronized following the (RFC 1305) Network Time Protocol, or (RFC 5905) Network Time Protocol Version 4) that the medication administration information was verified and/or submitted to the patient's record (*this information will be used in the DTR170.314.a.16 – 2: Electronically Record the Right Documentation of Medication Administration test*)

2014 Edition
Test Procedure for §170.314.a.16 Electronic medication administration record –
inpatient setting only
For Public Comment ■ September 21, 2012

The Office of the National Coordinator for
Health Information Technology

TE170.314.a.16 – 1.07: Using the ONC-supplied test data selected by the Tester in TE170.314.a.16 – 1.01, the Vendor-identified EHR function(s), and the second test patient, the Tester shall use (or shall observe, via remote capability, the EHR Vendor using) the EHR assistive technology as described by the Vendor to generate a "wrong patient" automated message during the electronic medication administration verification process (e.g., the patient identification bar code for the patient does not match the patient for whom the eMAR is being displayed by the EHR)

TE170.314.a.16 – 1.08: Using the ONC-supplied test data selected by the Tester in TE170.314.a.16 – 1.01 and the second test patient, the Tester shall use (or shall observe, via remote capability, the EHR Vendor using) the EHR assistive technology as described by the Vendor to generate at least one of each of the following "wrong" automated messages during the electronic medication administration verification process:

- "wrong medication" automated message (medication bar code does not match any of the medication orders entered for the test patient)
- "wrong dose" automated message (medication bar code matches a medication order entered for the test patient, but the dose indicated on the medication bar code does not match the dose for the medication order entered for the test patient)
- "wrong route" automated message (medication bar code matches a medication order entered for the test patient, but the route indicated on the medication bar code does not match the route for the medication order entered for the test patient)
- "wrong time" automated message (medication bar code matches a medication order entered for the test patient, but the time indicated by the synchronized clock in the EHR does not match the time ordered for the medication order entered for the test patient)

Inspection Test Guide

IN170.314.a.16 – 1.01: Using the ONC-supplied test data selected by the Tester in TE170.314.a.16 – 1.01 for the first test patient, the Tester shall verify for the ordered medications that the EHR assistive technology

- Verified the right patient
- Verified (for each of the medications administered)
  - The right medication
  - The right dose
  - The right route
  - The right time

2014 Edition
Test Procedure for §170.314.a.16 Electronic medication administration record –
inpatient setting only
For Public Comment ■ September 21, 2012

The Office of the National Coordinator for
Health Information Technology

IN170.314.a.16 – 1.02: Using the ONC-supplied test data selected by the Tester in TE170.314.a.16 – 1.01 for the second test patient, the Tester shall verify that the EHR assistive technology alerted the Tester about a "wrong patient"

IN170.314.a.16 – 1.03: Using the ONC-supplied test data selected by the Tester in TE170.314.a.16 – 1.01 for the second test patient, the Tester shall verify that the EHR assistive technology alerted the Tester about

- A wrong medication
- A wrong dose
- A wrong route
- A wrong time

DTR170.314.a.16 – 2: Electronically Record the Right Documentation of Medication Administration

Required Vendor Information

- As defined in DTR170.314.a.16 – 1, no additional information is required

Required Test Procedure:

TE170.314.a.16 – 2.01: For each of the medication administrations verified as "Right" for the first patient in the DTR170.314.a.16 – 1: Electronically Verify the 5 Rights of Medication Administration test, the Tester shall use (or shall observe, via remote capability, the EHR Vendor using) the Vendor-identified function(s) to electronically, automatically, and simultaneously record the date, time (utilizing a system clock that has been synchronized following the RFC 1305 NTPv3 or RFC 5905 NTPv4) and user identification information

TE170.314.a.16 – 2.02: Using the Inspection Test Guide, the Tester shall verify that the date, time and user identification information, for the medication administrations verified as "Right" for the first patient in the DTR170.314.a.16 – 1: Electronically Verify the 5 Rights of Medication Administration test, are recorded correctly and without omission

Inspection Test Guide:

IN170.314.a.16 – 2.01: Using the Vendor-identified authorized eMAR user's ID, the ONC-supplied test data selected by the Tester from TD170.314.a.16 – 2: Electronically Record the Right Documentation of Medication Administration, the dates and times noted in TE170.314.a.16 – 1.06, and viewing the first test patient's record in the EHR technology, the Tester shall

- Verify that the medication administration data verified/submitted in the DTR170.314.a.16 – 1: Electronically Verify the 5 Rights of Medication Administration test are stored accurately and without omission in the correct patient's record

2014 Edition
Test Procedure for §170.314.a.16 Electronic medication administration record –
inpatient setting only
For Public Comment ■ September 21, 2012

The Office of the National Coordinator for
Health Information Technology

▪ Verify that, for those administered medications, the correct date and time
(utilizing a system clock that has been synchronized following the (RFC
1305) Network Time Protocol, or (RFC 5905) Network Time Protocol
Version 4), and user identification are stored accurately and without
omission in the correct patient's record

TEST DATA

Test data are provided with the test procedure to ensure that the functional and interoperability
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-
Accredited Testing Laboratories (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 tester determines that the Vendor-selected message format requires some modification to
  the test data.
- The Tester determines that the Vendor product is sufficiently specialized that the 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 functional and interoperable requirements identified in the
  criterion can be adequately evaluated for conformance and that the test data provides a
  comparable level of robustness.

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 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

2014 Edition
Test Procedure for §170.314.a.16 Electronic medication administration record –
inpatient setting only
For Public Comment ■ September 21, 2012

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.

CONFORMANCE TEST TOOLS

None

Document History

Version Number	Description	Date Published
1.0	Released for public comment	September 21, 2012