



The Office of the National Coordinator for
Health Information Technology

ONC HIT Certification Program

Overview of ONC Health IT Certification Program and Test Method

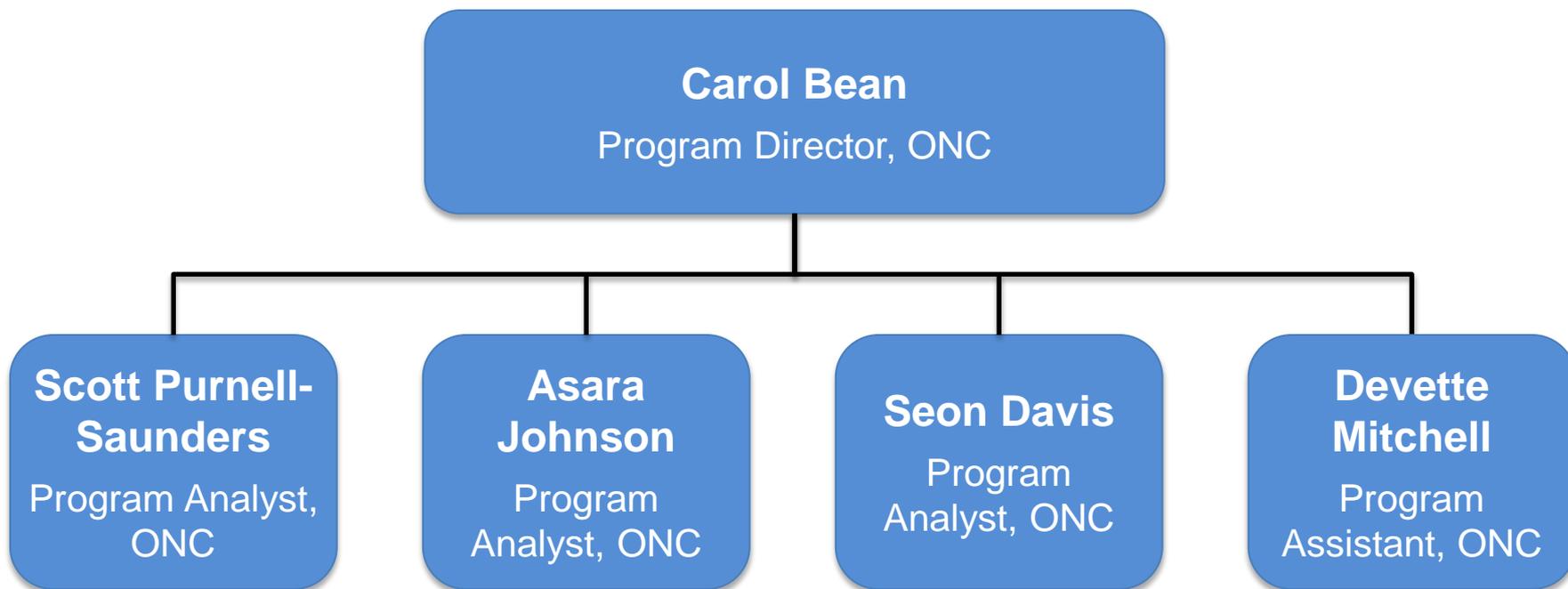
Carol Bean, Ph.D.

Director, Office of Certification
Office of the National Coordinator for Health IT

Technical Workshop
November 13, 2012



ONC – Office of Certification





Session One and Session Two

- ONC HIT Certification Program
- CHPL 2.1 and CHPL 3.0
- 2014 Test Method Development
- 2014 Test Scenarios
- 2014 Test Method Review



ONC HIT Certification Program



ONC HIT Certification Program

On October 4, 2012, the Temporary Certification Program sunsetted and the ONC HIT Certification Program began.

ONC HIT Certification Program Transition

- Name Change: Permanent Certification Program = ONC HIT Certification Program
- New Structure: ONC, NVLAP, ANSI, ATLS, and ACBs
- Separate testing and certification entities
- No impact on Temporary Program certifications

ONC HIT Certification Program – Participants



ONC

Office of the National Coordinator (ONC), Office of Certification manages the ONC HIT Certification Program.

NVLAP

National Voluntary Laboratory Accreditation Program (NVLAP), administered by the National Institute of Standards and Technology (NIST), accredits Accredited Testing Laboratories (ATLs).

ONC-AA

ONC-Approved Accreditor (ONC-AA) accredits and oversees ONC-Authorized Certification Bodies (ONC-ACBs). *Note: There is only one ONC-AA at a time.*

ATL

NVLAP Accredited Testing Laboratory (ATL) tests Health IT (HIT), including Complete EHRs and/or EHR Modules. *Note: There can be multiple ATLs.*

ONC-ACB

ONC-Authorized Certification Body (ONC-ACB) certifies HIT, including Complete EHRs and/or EHR Modules. *Note: There can be multiple ACBs.*

Developer/Vendor

Creator(s) of HIT, including Complete EHRs and/or EHR Modules.

ONC HIT Certification Program – ATLs and ACBs



NVLAP – Accredits Testing Laboratories (ATLs)

- Certification Commission for HIT (CCHIT)
- Drummond Group, Inc.
- ICSA Laboratories, Inc.
- InfoGard Laboratories, Inc.
- SLI Global Solutions

ANSI – Accredits Certification Bodies (ACBs)

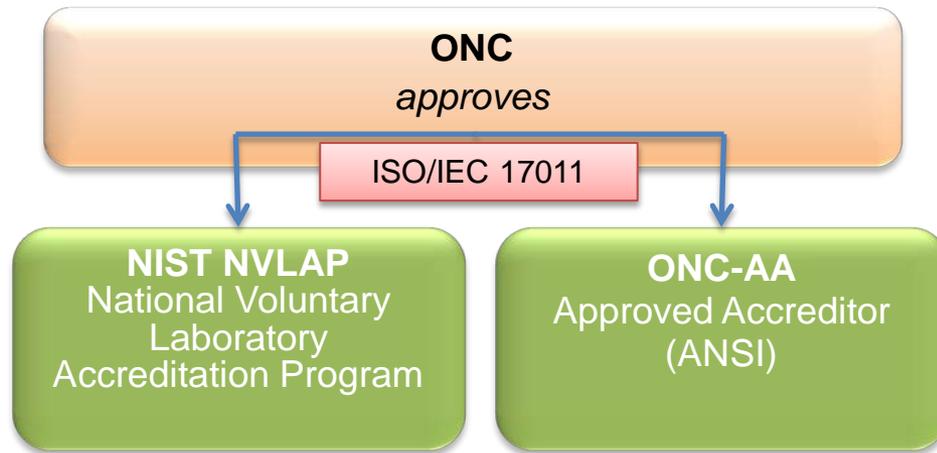
- Certification Commission for HIT (CCHIT)
- Drummond Group, Inc.
- ICSA Laboratories, Inc.
- InfoGard Laboratories, Inc.
- Orion Register, Inc.

ONC HIT Certification Program – Office of the National Coordinator

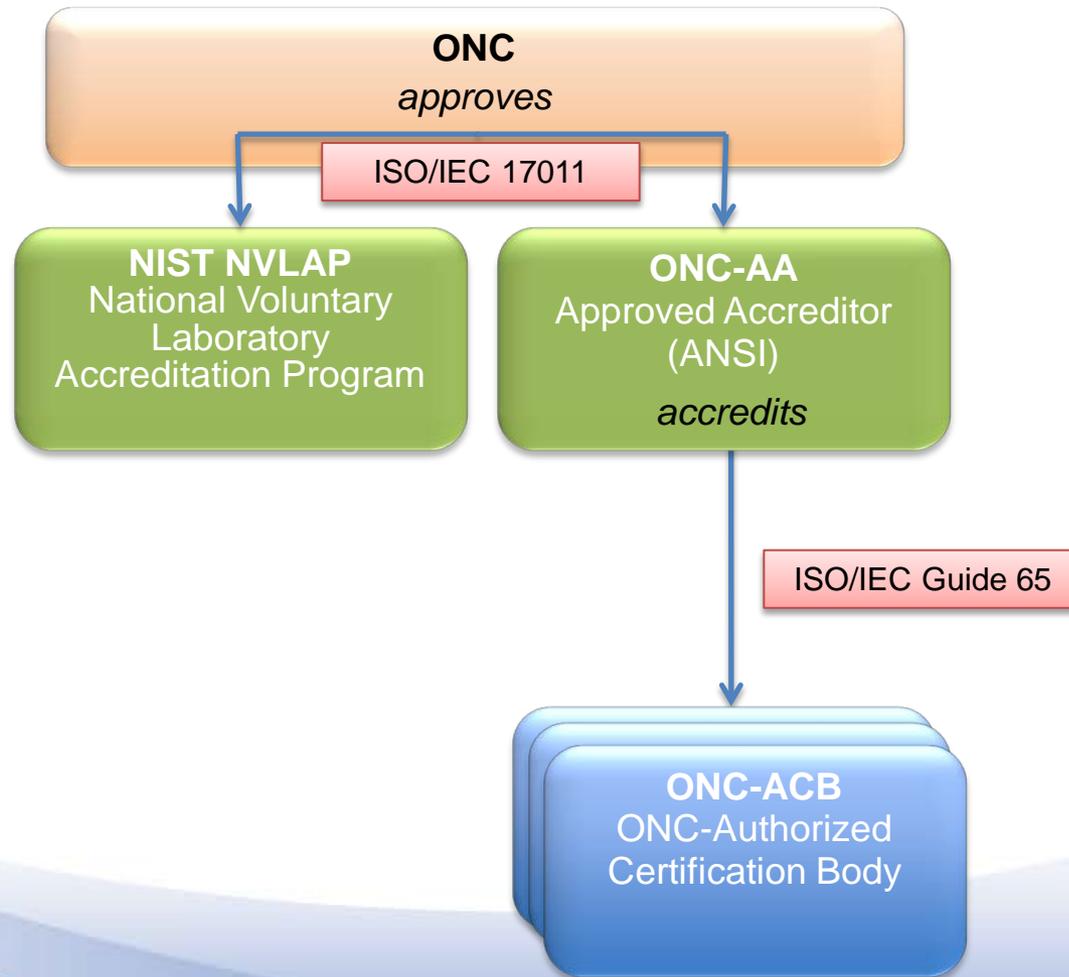


ONC

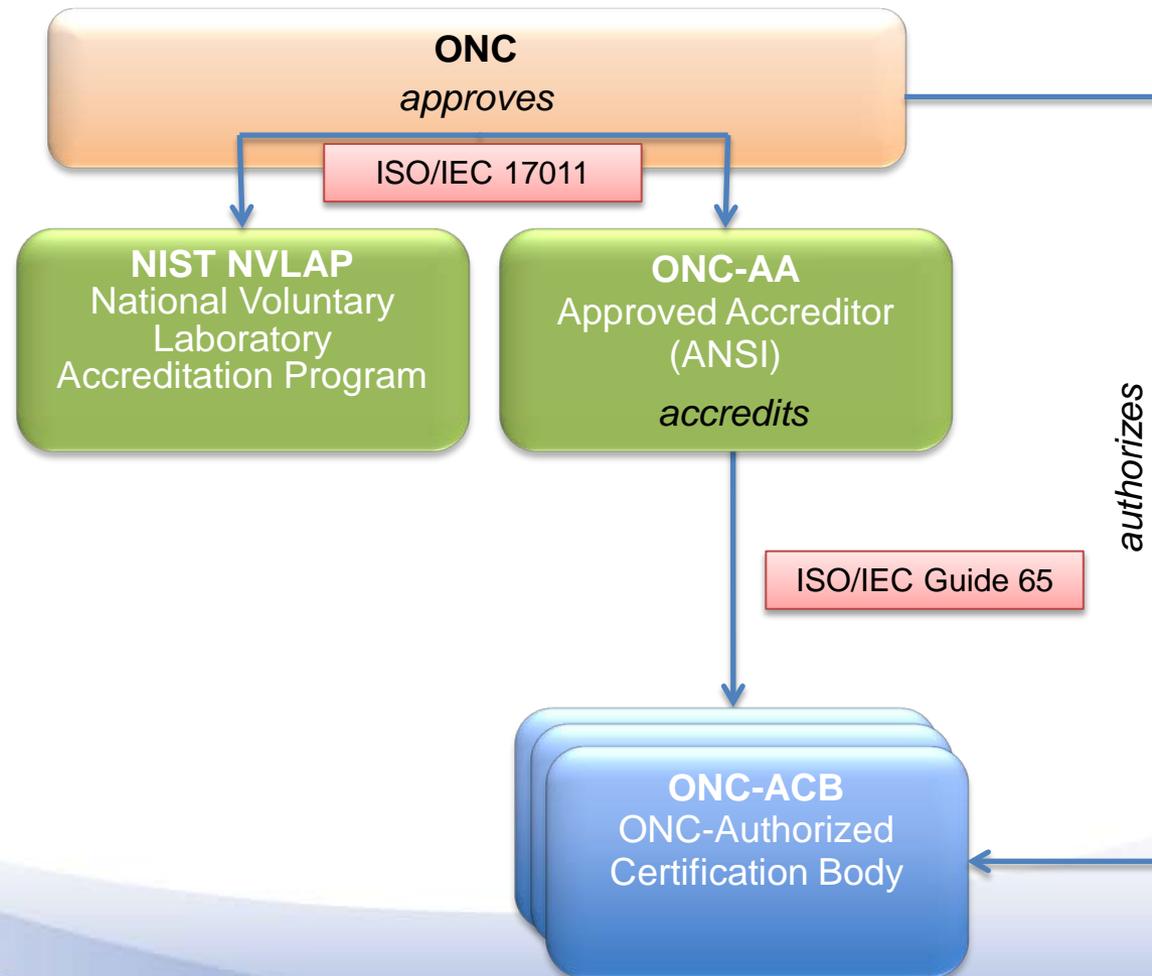
ONC HIT Certification Program – NVLAP and ONC-AA (ANSI)



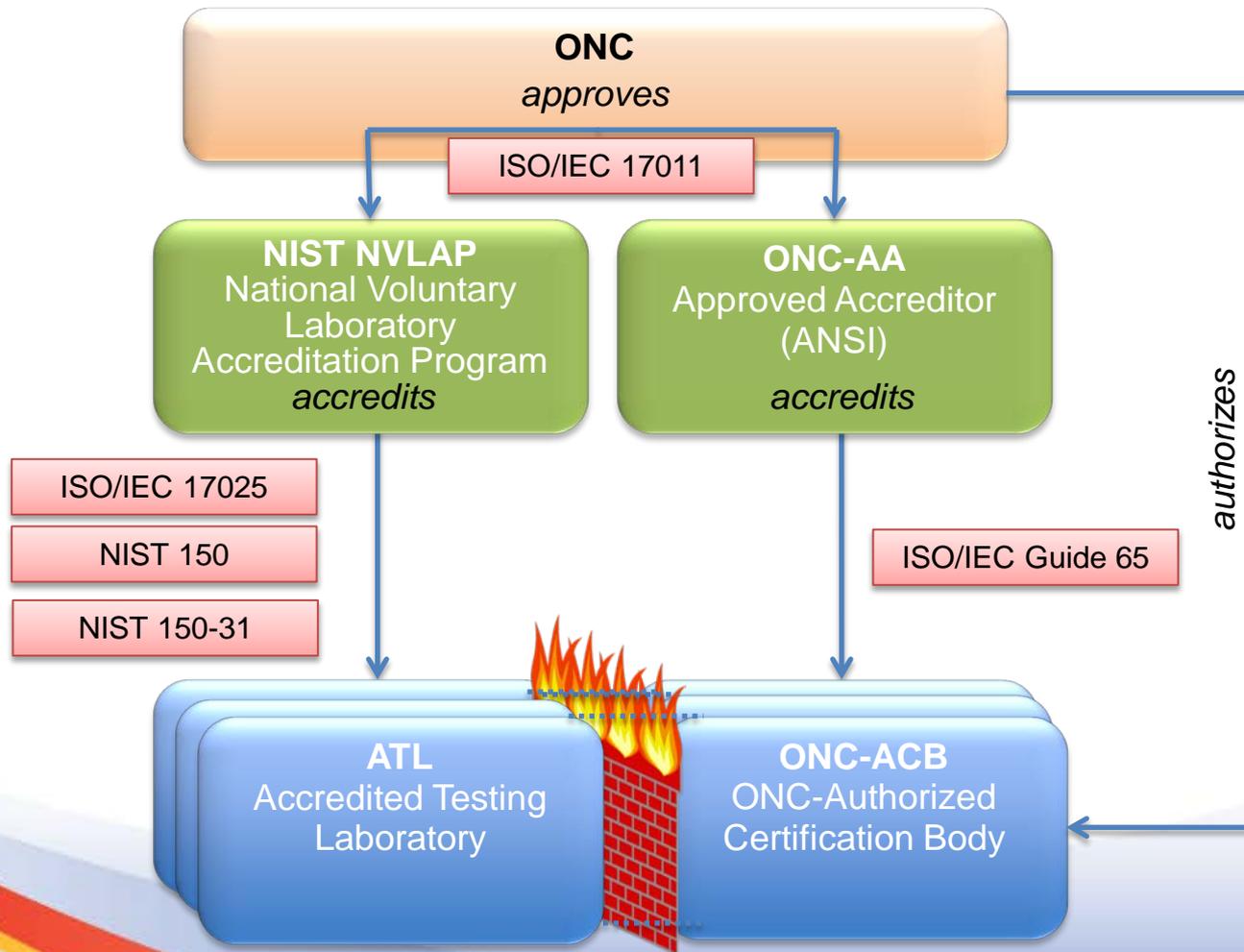
ONC HIT Certification Program – ONC-AA Accredits ONC-ACBs



ONC HIT Certification Program – ONC Authorizes ONC-ACBs



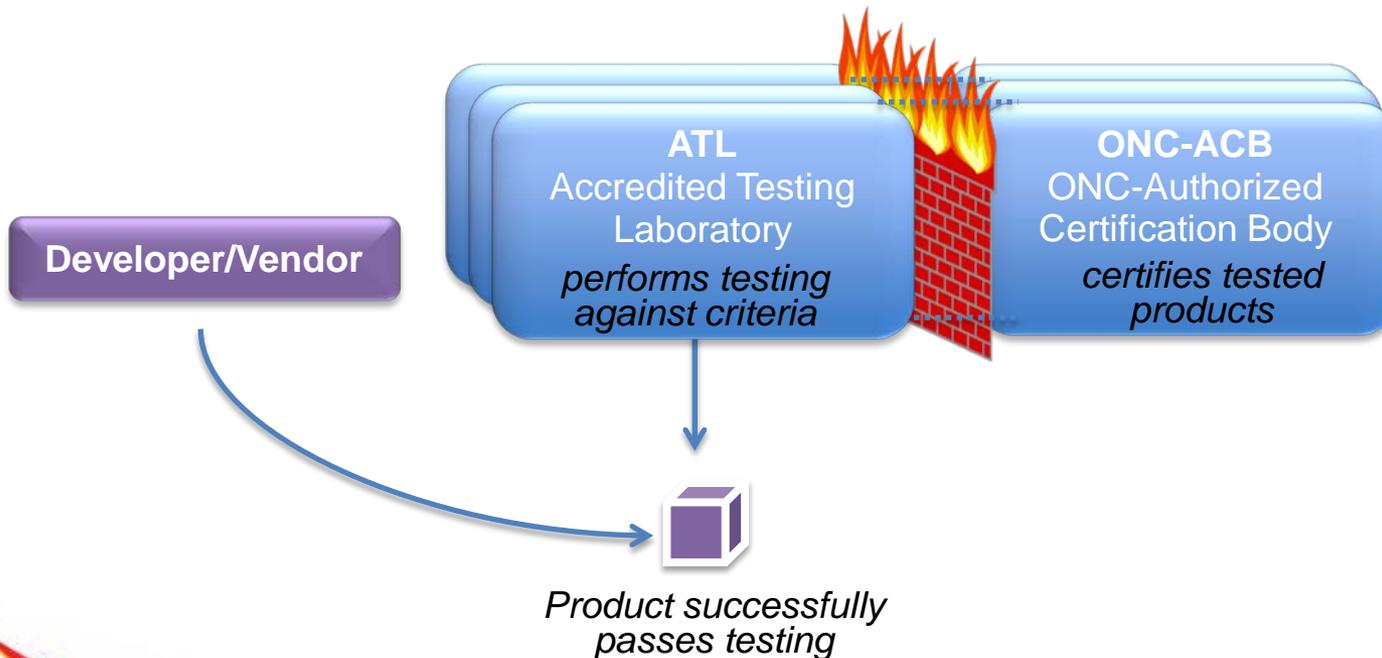
ONC HIT Certification Program – NVLAP Accredits ATLs



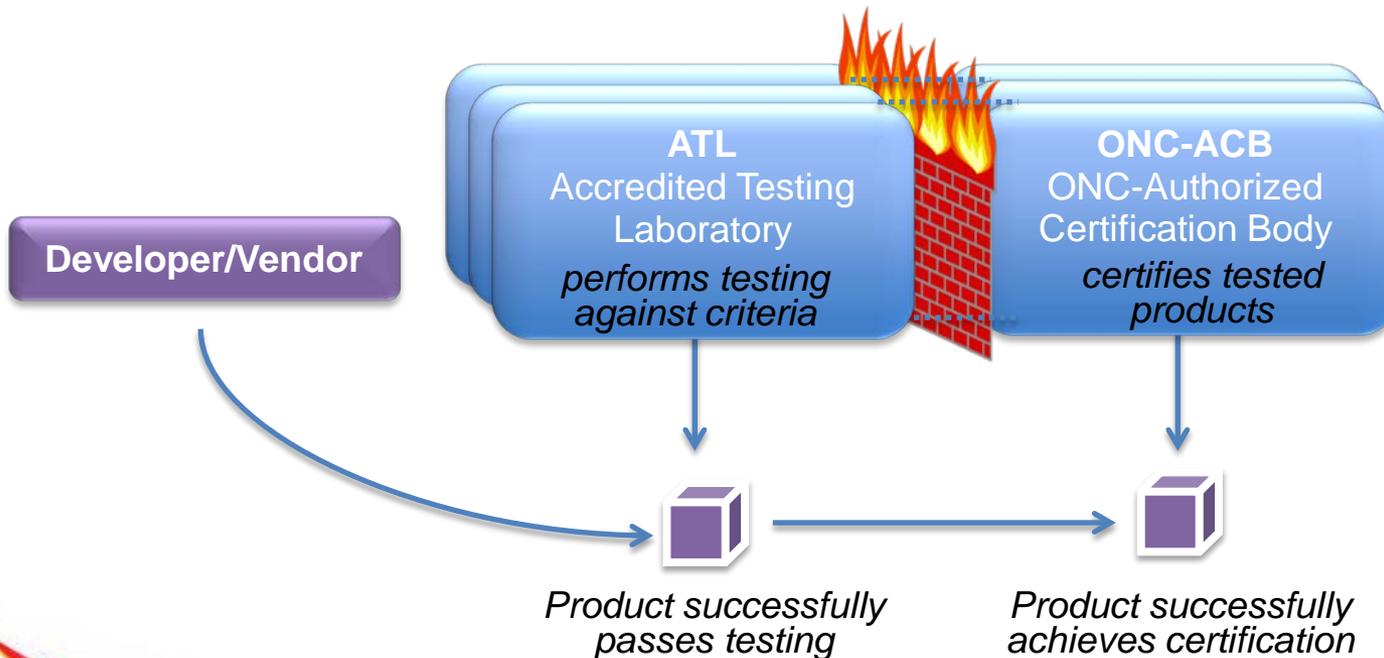
ONC HIT Testing and Certification – Developers and Vendors



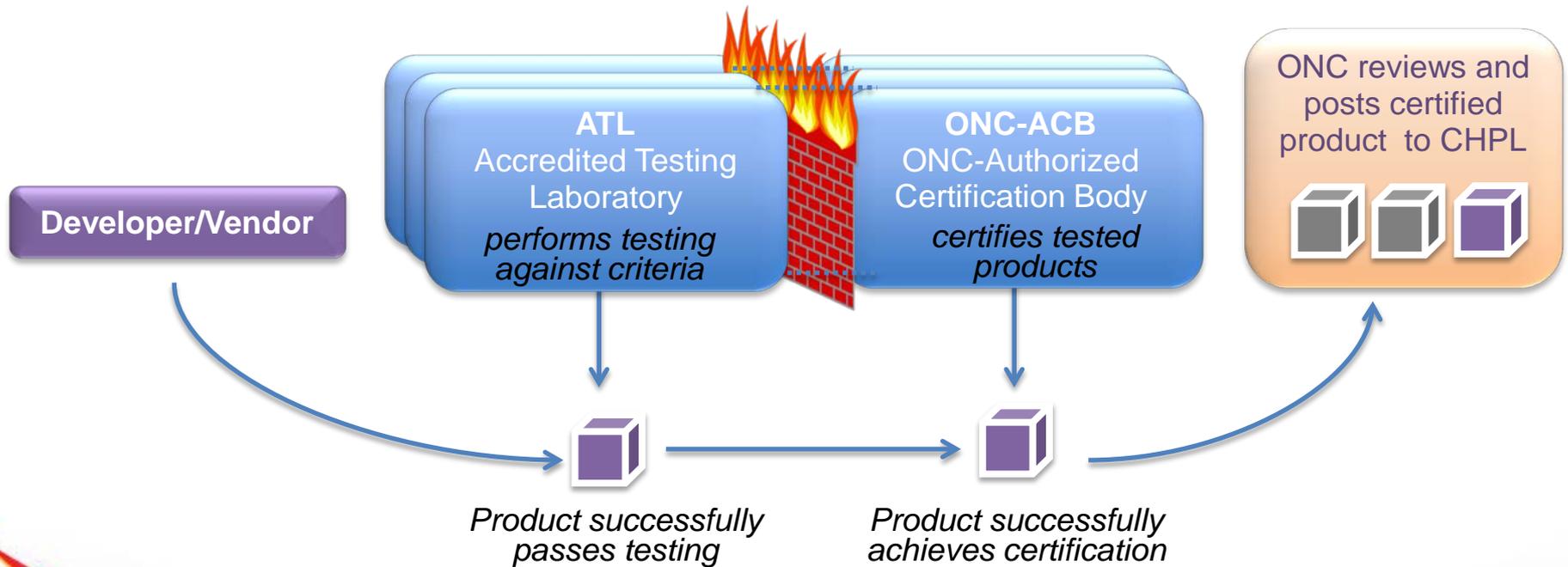
ONC HIT Testing and Certification – ATL Tests EHR Technology



ONC HIT Testing and Certification – ONC-ACB Certifies EHR Technology



ONC HIT Testing and Certification – ONC Posts CEHRT to CHPL





Certified Health IT Product List (CHPL)

Certified Health IT Product List



Purpose

The Certified Health IT Product List (CHPL), managed by ONC, provides the authoritative, comprehensive listing of certified Complete Electronic Health Records (EHRs) and EHR Module(s)

Process

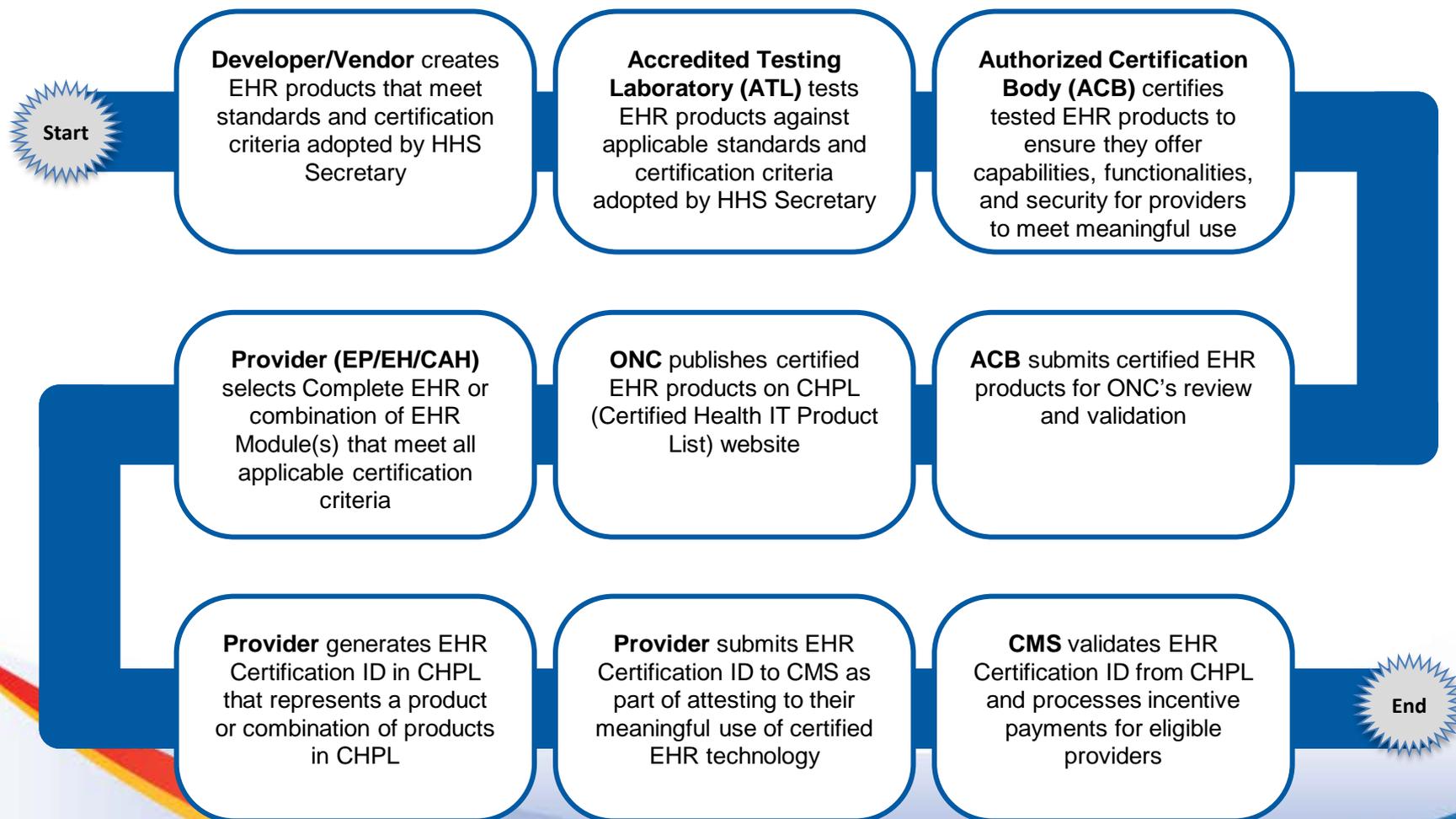
ONC-ACBs submit newly certified EHR products and EHR product updates to ONC on a weekly basis, and ONC posts the EHR products on the CHPL



<http://healthit.gov/chpl>



CHPL Stakeholder Process Overview





CHPL Users

Certified Health IT Product List (CHPL) Users

EHR Vendors

- Demonstrate that their EHR technology meets the standards and certification criteria adopted by the HHS Secretary
- Promote EHR products that align with providers practice size, medical specialty, and clinical goals

Providers (EP/EH/CAH)

- Find an EHR product or combination of products that are certified for meaningful use
- Find EHR modules that allow practices with existing software to add new functionality
- List self-developed or custom-developed EHR technology on CHPL after it's tested and certified
- Document the products used as part of the attestation process for CMS incentive payments

CMS

- Accepts EHR CERT IDs generated on CHPL for attestation purposes under the EHR Incentive Programs
- Uses CHPL data to track trends in the marketplace by vendor, product, practice type, ACB, and product type (complete vs. modular)



CMS EHR Certification ID

CMS EHR Certification ID vs. CHPL Product Number:

CHPL Product Number: Product number assigned to an EHR product by the certification body that certified the product. *Used within ONC.*

CMS EHR Certification ID: Generated by the CHPL. *Needed for the Meaningful Use attestation process with CMS.*

Navigating CHPL (2011 Certification) – Select Practice Type



Select Practice Type

- Ambulatory or Inpatient

USING THE CHPL WEBSITE

To browse the CHPL and review the comprehensive listing of certified products, follow the steps outlined below:

1. Select your practice type by selecting the Ambulatory or Inpatient buttons below
2. Select the "Browse" button to view the list of CHPL products

To obtain a CMS EHR Certification ID, follow the steps outlined below:

1. Select your practice type by selecting the Ambulatory or Inpatient buttons below
2. Search for EHR Products by browsing all products, searching by product name or searching by criteria met
3. Add product(s) to your cart to determine if your product(s) meet 100% of the required criteria
4. Request a CMS EHR Certification ID for CMS registration or attestation from your cart page

STEP 1: SELECT YOUR PRACTICE TYPE

Ambulatory Practice Type Inpatient Practice Type

Navigating CHPL (2011 Certification) – Search EHR Products



Search EHR Products

- Browse all products
- Search by name or CHPL product number
- Search by certification criteria

STEP 2: SEARCH FOR CERTIFIED EHR PRODUCTS

Use the browse all products, search by product name or search by criteria met to search for certified EHR products.

Browse All Ambulatory Products

Browse

Search by Name or CHPL Product Number:

Select search type:

Product Name

Search

Search for:

Search by Criteria Met

Search

Navigating CHPL (2011 Certification) – Add Products to Cart



Add Products to Cart

- Can add multiple products to cart
- *Note: products are purchased from Vendors, not on CHPL*

STEP 3: ADD PRODUCTS TO YOUR CART

To add products to your cart, select the "Add to Cart" link in the far-right column. After adding a product to your cart, you will be directed to your cart page. Once on the cart page you can view the criteria met by the product(s) in your cart. Once the product(s) in your cart meet 100% of the required criteria you can obtain a CMS EHR Certification ID.

You can sort on any column in the table below. To sort, click on the column header and the arrow will confirm you are sorting in ascending or descending order.

Matching Product		<input type="checkbox"/> See Complete Products Only				
Certifying ATCB	Vendor	Product	Product Version#	Product Classification	Additional Software Required	
Drummond Group Inc.	Claydata® LLC	+Putty Health™ v2.0: Secure Inpatient & Ambulatory EMR/EHR Telemedicine, Emergency & Aged Health Care Systems	v2.0	Modular EHR		Add to Cart

Navigating CHPL (2011 Certification) – Review Certification Summary



Select Practice
Type

Search EHR
Products

Add Products
to Cart

Review
Certification
Summary

Get CMS EHR
Certification ID

Review Certification Summary

- Products must meet 100% of required criteria for the selected practice setting
- If selected product(s) do not meet all certification criteria, provider cannot generate CMS EHR CERT ID

STEP 4: REQUEST CMS EHR CERTIFICATION ID

Certification Bar Summary

The bar below provides a summary of the criteria that are met by items in your cart. Criteria highlighted in blue have been met by products in the cart, criteria in gray have not.

Note: Certification criterion 170.302(w) is optional for the purposes of certification. If w is gray in the bar below, the product(s) in your cart can still meet 100% of the required certification criteria.

Place your mouse over the individual letters to learn more about each criterion.

General Criteria (170.302) Inpatient Criteria (170.306)

a b c d e f g h i j k l m n o p q r s t u v w a b c d e f g h i

Navigating CHPL (2011 Certification) – Get CMS EHR Certification ID



Select Practice
Type

Search EHR
Products

Add Products
to Cart

Review
Certification
Summary

Get CMS EHR
Certification ID

CMS EHR Certification ID

- Generates ID specific to product combination
- ID used by health care providers for CMS attestation

Requesting Your CMS EHR Certification ID

If the products in your cart meet 100% of the required criteria, you can now obtain a CMS EHR Certification ID.

If the products in you cart do not meet 100% of the required criteria, select the "Return to Search" link and continue adding products to your cart until your cart meets 100% of the required criteria.

Get CMS EHR Certification ID

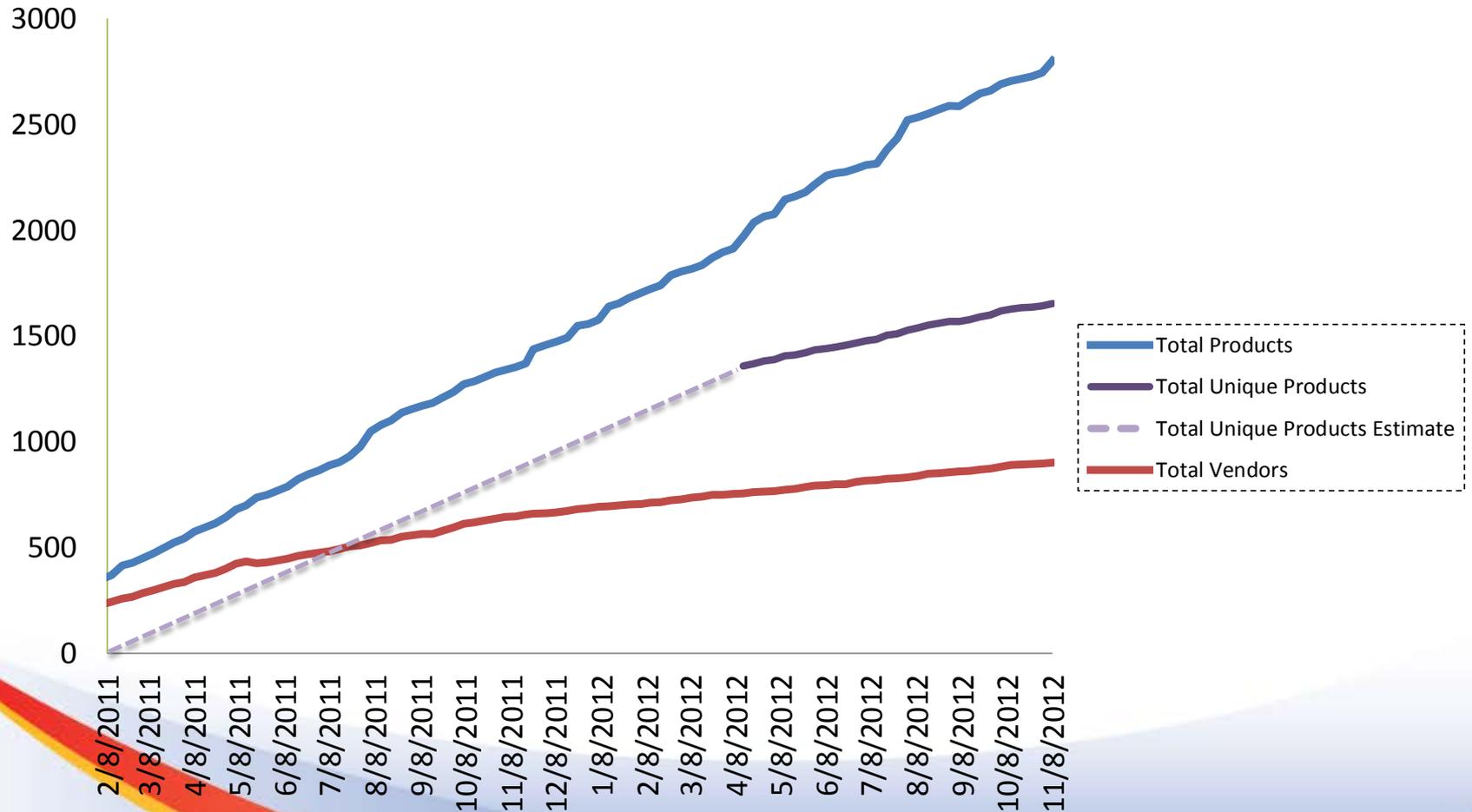
Percentage of criteria currently met:100%



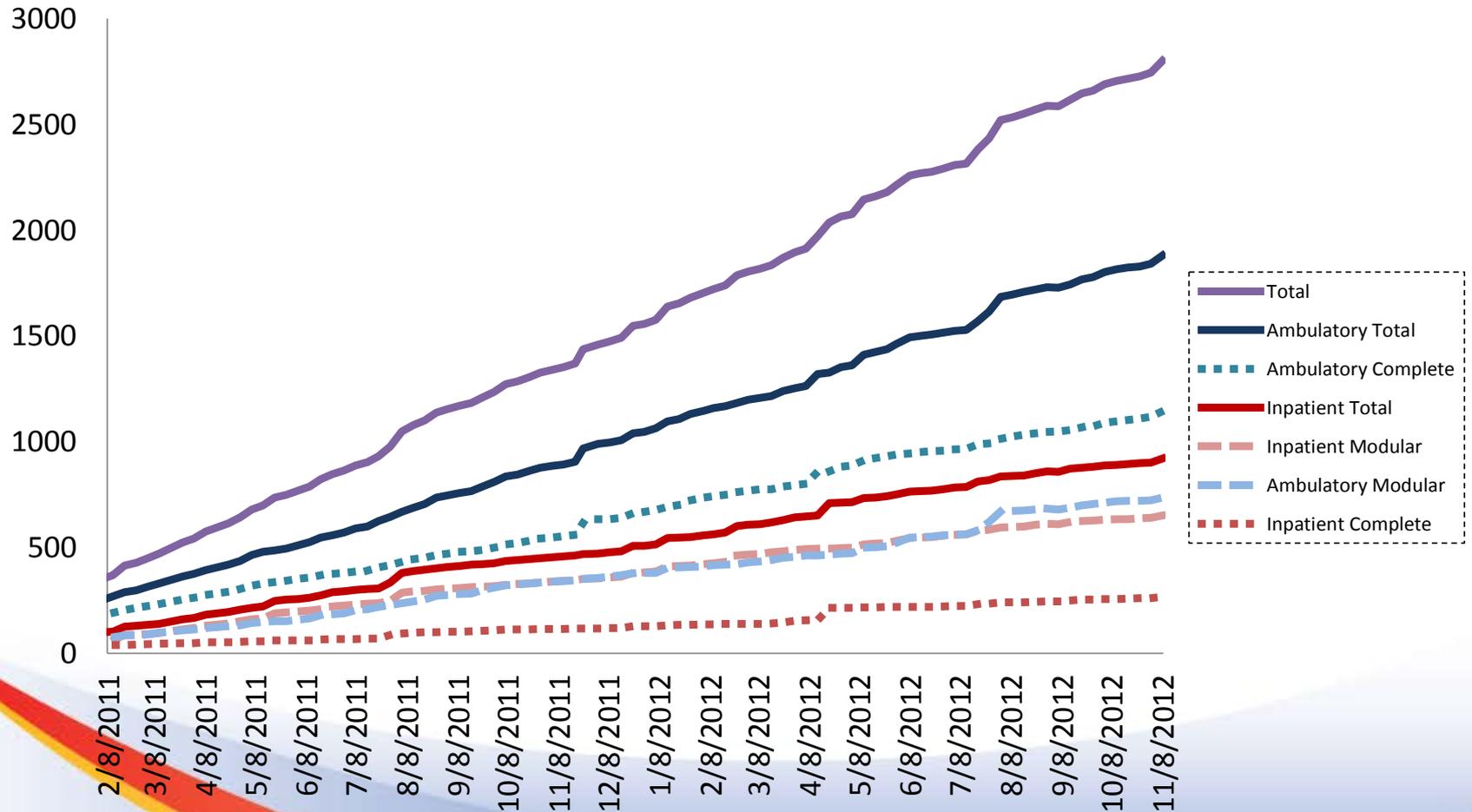
Hybrid Certification

- All products that are certified to meet the Inpatient Criteria now satisfy all the Ambulatory Criteria
- EPs who practice in both outpatient and inpatient settings can generate a CMS EHR Certification ID to participate in the CMS EHR Incentive Programs

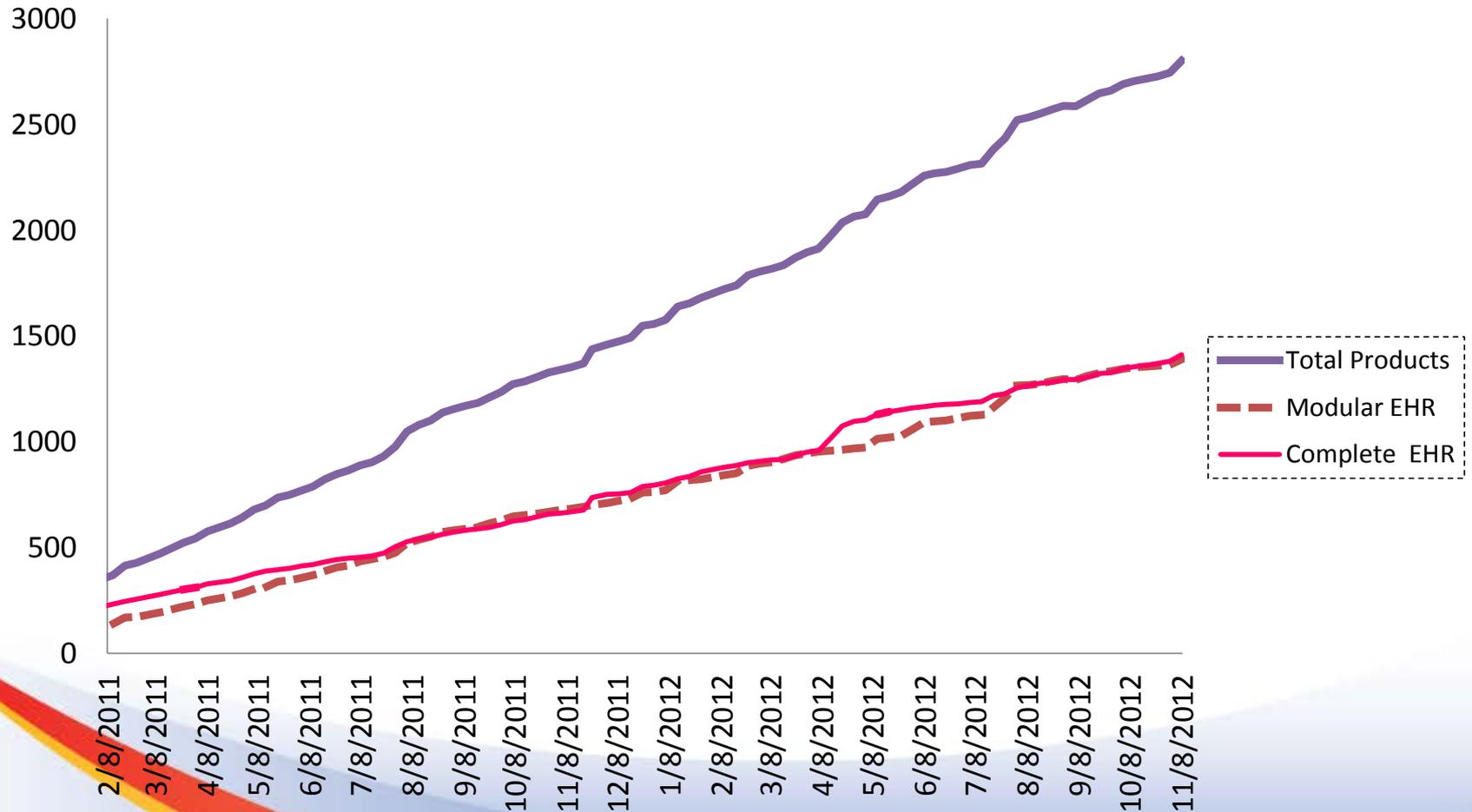
CHPL Reporting – Product and Vendor Trends *(as of 11/08/12)*



CHPL Reporting – Ambulatory and Inpatient Trends *(as of 11/08/12)*



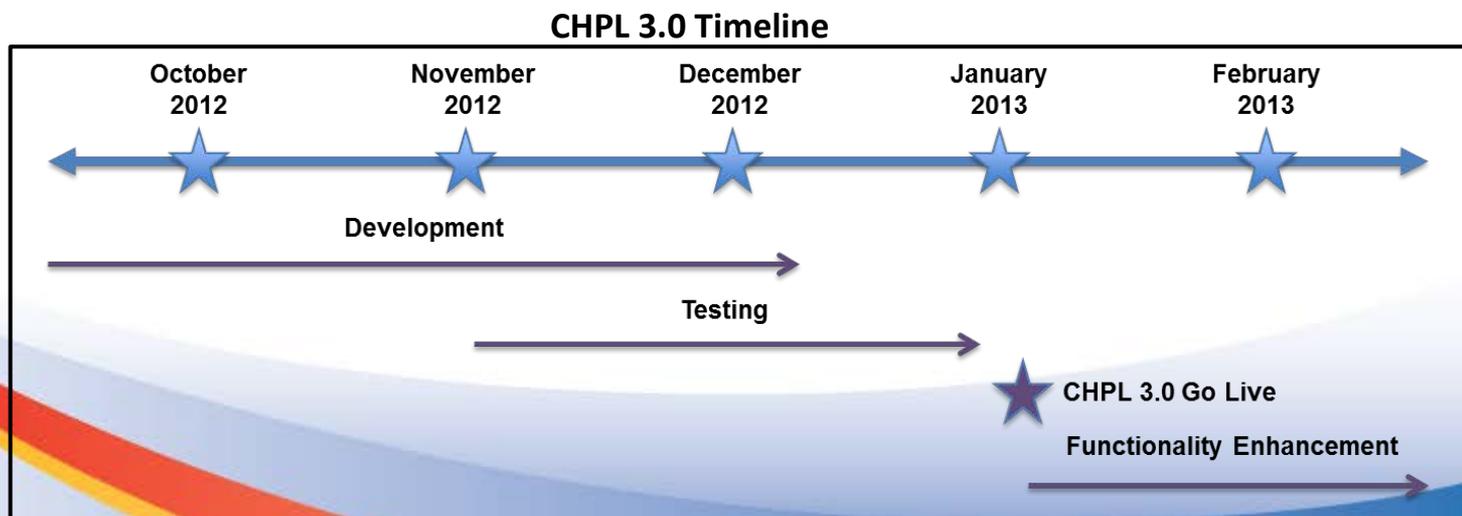
CHPL Reporting – Complete and Modular Trends *(as of 11/08/12)*





Introducing CHPL 3.0

- CHPL 3.0 will go live in January, 2013
- EPs, EHs, and CAHs will be able to use EHR technology or a combination of EHR technology that is certified to :
 - 2011 Edition certification criteria; or
 - 2014 Edition certification criteria; or
 - A combination of 2011 Edition and 2014 Edition EHR certification criteria



CHPL 3.0 Changes – 2013 EHR Certification



- For Federal fiscal year (FY) and calendar year (CY) up to and including 2013, eligible providers can use EHR technology that is certified to 2011 Edition certification criteria AND/OR equivalent 2014 Edition certification criteria

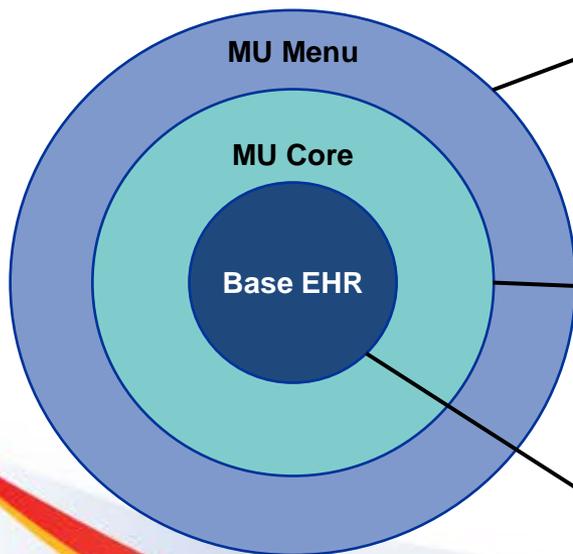
Equivalency Table

2011 Edition		2014 Edition		Certification Criterion Name
<i>Ambulatory</i>	<i>Inpatient</i>	<i>Ambulatory</i>	<i>Inpatient</i>	
§ 170.304(a)	§ 170.306(a)	§ 170.314(a)(1)		Computerized provider order entry
§ 170.302(a)		§ 170.314(a)(2)		Drug-drug, drug-allergy interaction checks
§ 170.304(c)	§ 170.306(b)	§ 170.314(a)(3)		Demographics
§ 170.302(f)		§ 170.314(a)(4)		Vital signs, BMI, & growth charts
§ 170.302(c)		§ 170.314(a)(5)		Problem list
§ 170.302(d)		§ 170.314(a)(6)		Medication list
§ 170.302(e)		§ 170.314(a)(7)		Medication allergy list
§ 170.304(d)	§ 170.306(c)	§ 170.314(a)(8)		Clinical decision support

CHPL 3.0 Changes – 2014 EHR Certification



Starting in 2014, all EHR Incentive Programs participants will have to adopt certified EHR technology that meets ONC's Standards & Certification Criteria adopted in 2014 Final Rule



EP/EH/CAH would only need to have EHR technology with capabilities certified for the MU menu set objectives & measures for the stage of MU they seek to achieve

EP/EH/CAH would need to have EHR technology with capabilities certified for the MU core set objectives & measures for the stage of MU they seek to achieve unless the EP/EH/CAH can meet an exclusion

EP/EH/CAH must have EHR technology with capabilities certified to meet the Base EHR definition

CHPL 3.0 Changes – CHPL 2014 Edition EHR Certification ID

Base EHR Definition

- 21 certification criteria (20 = required, 1 = optional) associated with a Base EHR
 - Certification to Privacy & Security policy not required; policy outcome is now reflected in the Base EHR definition

Clinical Quality Measure – EP

- EHR technology to be certified to ≥ 9 CQMs
 - ≥ 6 from CMS' recommended core set
 - ≥ 3 domains from the set selected by CMS for EPs

Clinical Quality Measure – EH/CAH

- EHR technology to be certified to ≥ 16 CQMs from CMS' selected set for EH/CAH
 - ≥ 3 domains from the set selected by CMS for EH/CAHs

**CHPL 2014
Edition EHR
Certification ID**

CHPL 3.0 Changes – CMS EHR Certification ID



An Eligible Professional (EP) or Eligible Hospital (EH/CAH) that chooses to participate in the EHR Incentive Programs must obtain a CMS EHR Certification ID from CHPL. The CMS EHR Certification ID must be submitted as part of the attestation process for either the Medicare or Medicaid incentive program.

CMS EHR Certification ID is a 15-digit alphanumeric string that represents a product or combination of product(s) in CHPL

	<u>2011</u>	<u>2013</u>	<u>2014</u>
CMS EHR CERT ID	E.g., A000001CFES9EAB	3 rd , 4 th , and 5 th digits of the 15-digit alphanumeric string will be denoted by “H”, “1”, and “3” respectively E.g., A0 <u>H13</u> 01CFES9EAB	3 rd , 4 th , and 5 th digits of the 15-digit alphanumeric string will be denoted by “1”, “4”, and “E” respectively E.g., A0 <u>14E</u> 01CFES9EAB

CHPL 3.0 Changes – ACB Data Upload & Reporting



ACB Data Upload

- Updated ACB data upload template will be available with 2014 edition Certification Criteria and CQM fields
- ACB data upload process will not change for new, update, and delete records
- Additional guidance on ACB data upload will be communicated in mid-December 2012

Reporting

- Providers can download 'CHPL Product Information' report from the CHPL site
- Report is updated weekly and contains all CHPL data

Navigating CHPL 3.0 – Select Attestation Year



Attestation Year

- 2 new doors added on CHPL home page: 2013 (combination of 2011 and 2014) & 2014
- Providers to select the door corresponding to the attestation year of interest

STEP 1: TO WHICH CRITERIA ARE YOU ATTESTING?

[Click here for 2011](#)

[Click here for 2011 & 2014 Hybrid](#)

[Click here for 2014](#)

Navigating CHPL 3.0 – Search EHR Products

Select
Attestation Year

**Search EHR
Products**

Add Products
to Cart

Review
Certification
Summary

Get CMS EHR
Certification ID

2013

- Select 'Practice Type' prior to searching for certified EHR products
- Search functionality same as 2011
- All products (2011 + 2014) will be displayed in search results

2014

- Enhancements to search functionality:
 - Search by CQMs met
 - Search by Product Classification (complete/modular)
- Only 2014 products will be displayed in search results

STEP 2: SEARCH FOR CERTIFIED EHR PRODUCTS

Use the browse all products, search by product name or search by criteria met to search for certified EHR products.

Browse All Products

Search by Name or CHPL Product Number:

Select search type:

Product Name

Search for:

Search by Criteria Met

Search by Measures Met

Only in 2014

Navigating CHPL 3.0 – Add Product to Cart



2013

- Can add multiple products to cart

2014

- Can add multiple products to cart
- Practice Setting (ambulatory/inpatient) filter above the search results table

STEP 3: ADD PRODUCTS TO YOUR CART

To add products to your cart, select the "Add to Cart" link in the far-right column. After adding a product to your cart, you will be directed to your cart page. Once on the cart page you can view the criteria met by the product(s) in your cart. Once the product(s) in your cart meet 100% of the required criteria you can obtain a CMS EHR Certification ID.

You can sort on any column in the table below. To sort, click on the column header and the arrow will confirm you are sorting in ascending or descending order.

Practice setting filter:

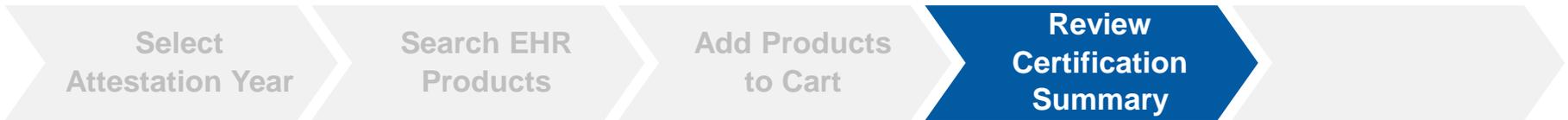
Ambulatory Inpatient Both

→ Only in 2014

See Complete Products Only

Certifying ATCB	Original Practice Setting	Vendor	Product	Product Version#	Product Classification	Additional Software Required	
Drummond Group Inc.	Ambulatory	MedCPU Inc.	Meaningful Use Advisor	1	Modular EHR	2014	Already in cart

Navigating CHPL 3.0 – Review Certification Summary



2013

- Products must meet 100% of required certification criteria for selected practice setting
- Graphical representation same as 2011

2014

- Products must meet Base EHR, and required CQMs, and CQM domains for at least one practice setting

Base EHR																			
A1	A3	A5	A6	A7	A8	B1	B2	B7	C1	C2	C3	D1	D2	D3	D4	D5	D6	D7	D8
CQM Domains																			
Efficient Use of Healthcare Resources					Clinical Process / Effectiveness				Patient Safety			Population / Public Health			Patient and Family Engagement			Care Coordination	
Core Ambulatory CQMs									Inpatient CQMs										
002	018	022	024	028	033	036	038	052	495	497	435	436	437	438	439	440	441	371	
069	108	418	419	421	TBD	TBD	TBD		372	373	374	375	376	142	469	164	163	639	
									147	527	528	453	496	338	480	716		1354	
Total number of Ambulatory CQMs met: ≥ 9									Total number of Inpatient CQMs met: ≥ 16										

Navigating CHPL 3.0 – Get CMS EHR Certification ID



CMS EHR Certification ID

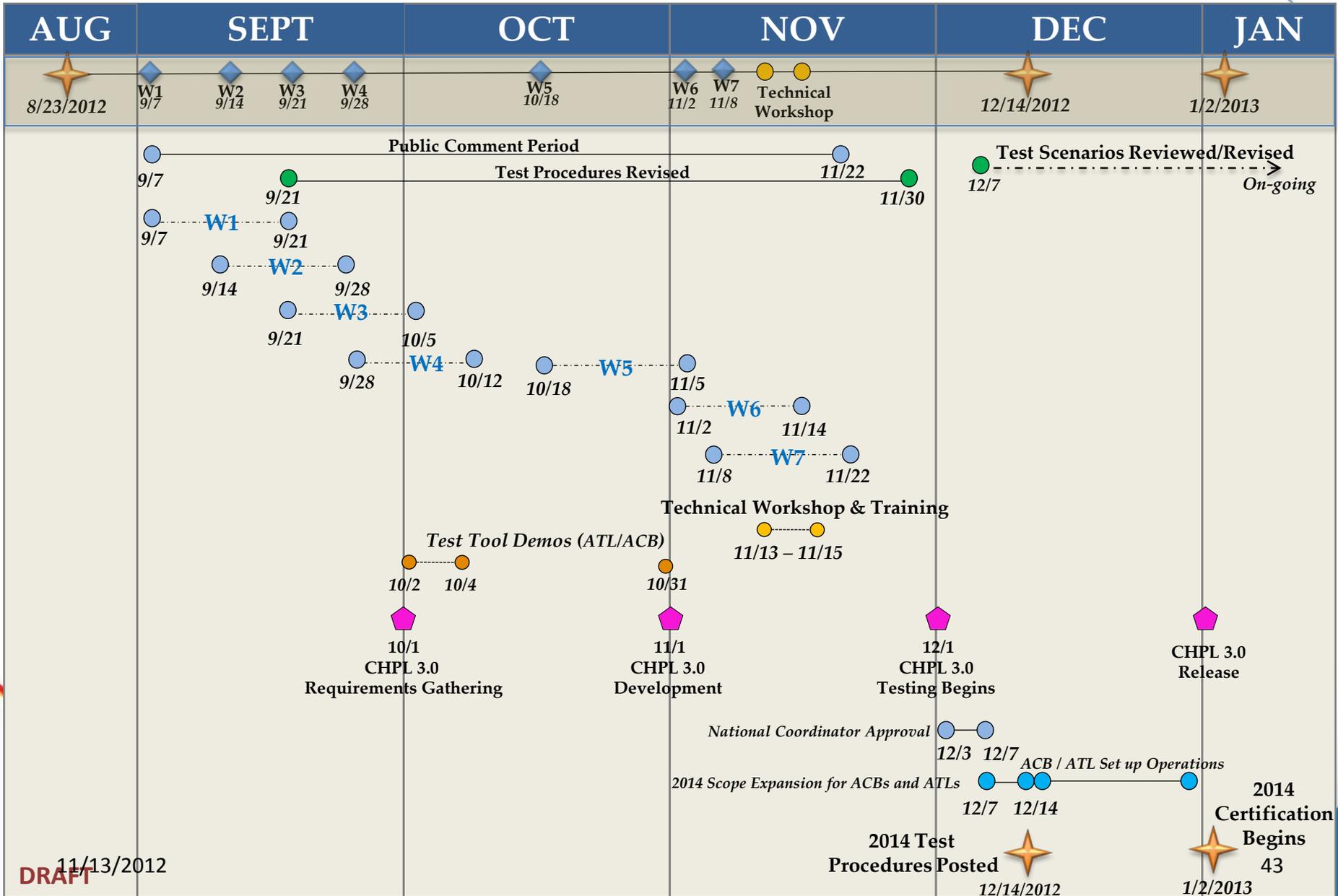
- Generates ID specific to product combination
- ID used by health care providers for CMS attestation

2013	2014
EOH130001PHLEAY	EO14E0001PEREAY



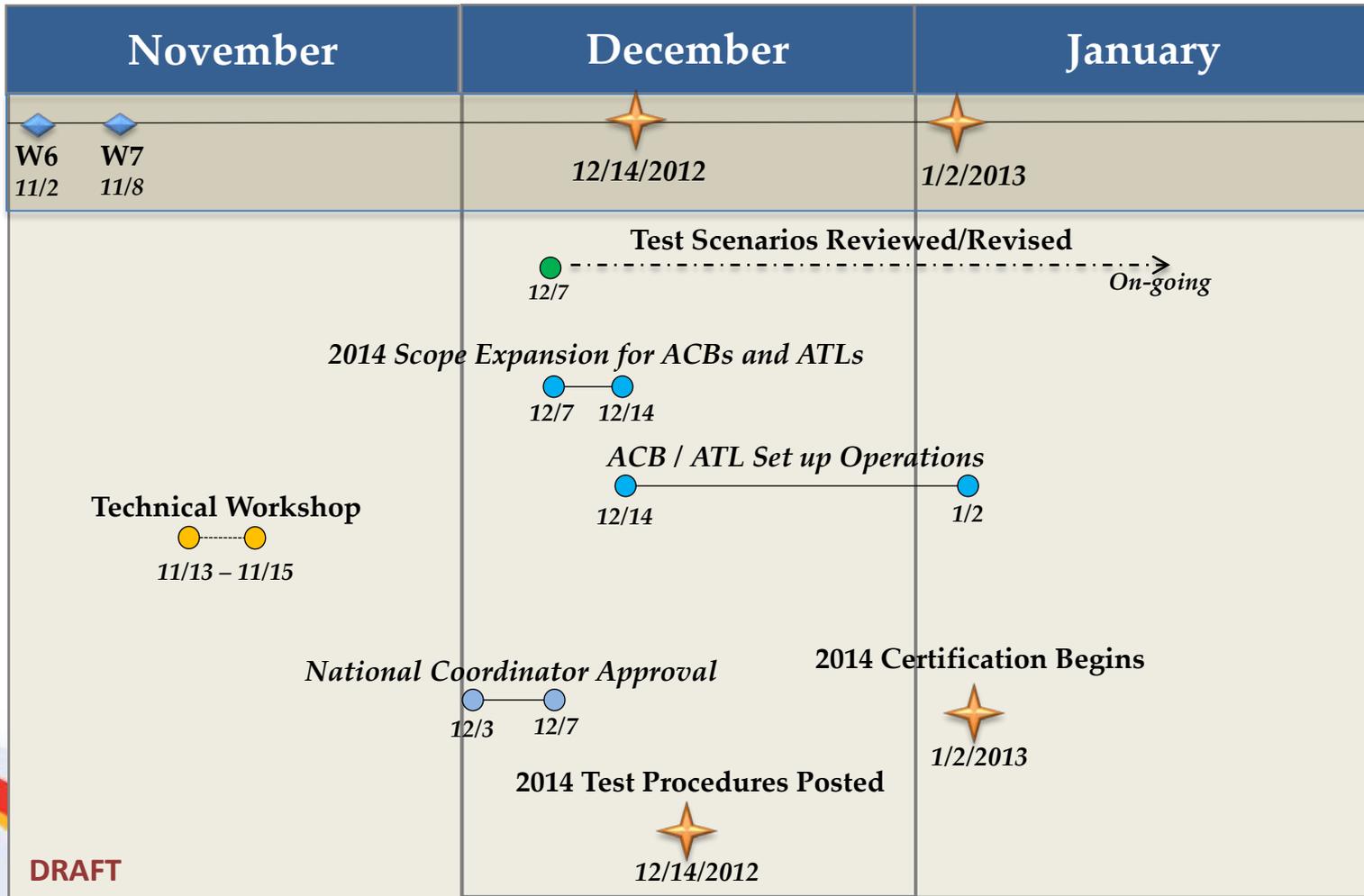
2014 Test Method Development

2014 Test Method Timeline





2014 Timeline – November to January



Test Method Development – 2014 Edition Technical Requirements



**Final Rule
Publication**

September 4, 2012

Final Rule Publication

- September 4, 2012
- Published in the Federal Register
- Defines the 2014 Edition Certification Criteria
- Aligns with CMS' Stage 2 MU

Test Method Development – Test Method Draft Development



**Final Rule
Publication**

**Draft Test
Method**

September 4, 2012

Sept. – Nov. 2012

Draft Test Method

- September – November 2012
- Evaluates conformance to 2014 Edition Certification Criteria
- Overseen by ONC's Office of Certification

Test Method Development – Public Review and Feedback



Public Review

- September 7 – November 22, 2012
- Request feedback/input from the public
- Draft Test Method posted on ONC's website in waves

Test Method Development – Revision and Training



Test Method Update

- September – November 2012
- Analyze public comments
- Update Test Method per public review
- ATL and ACB training and evaluation

Test Method Development – Approval by National Coordinator



Final Test Method

- Mid-December 2012
- National Coordinator approves final 2014 Edition Test Method
- Federal Register Notice
- Final Test Method posted on ONC's website

Test Method Development – Implementation



Implementation

- December 2012
- NVLAP and ANSI expand scope to 2014 Ed.
- ONC authorizes ACBs
- ATLS and ACBs begin operational implementation
- Testing and Certification begins in January 2013

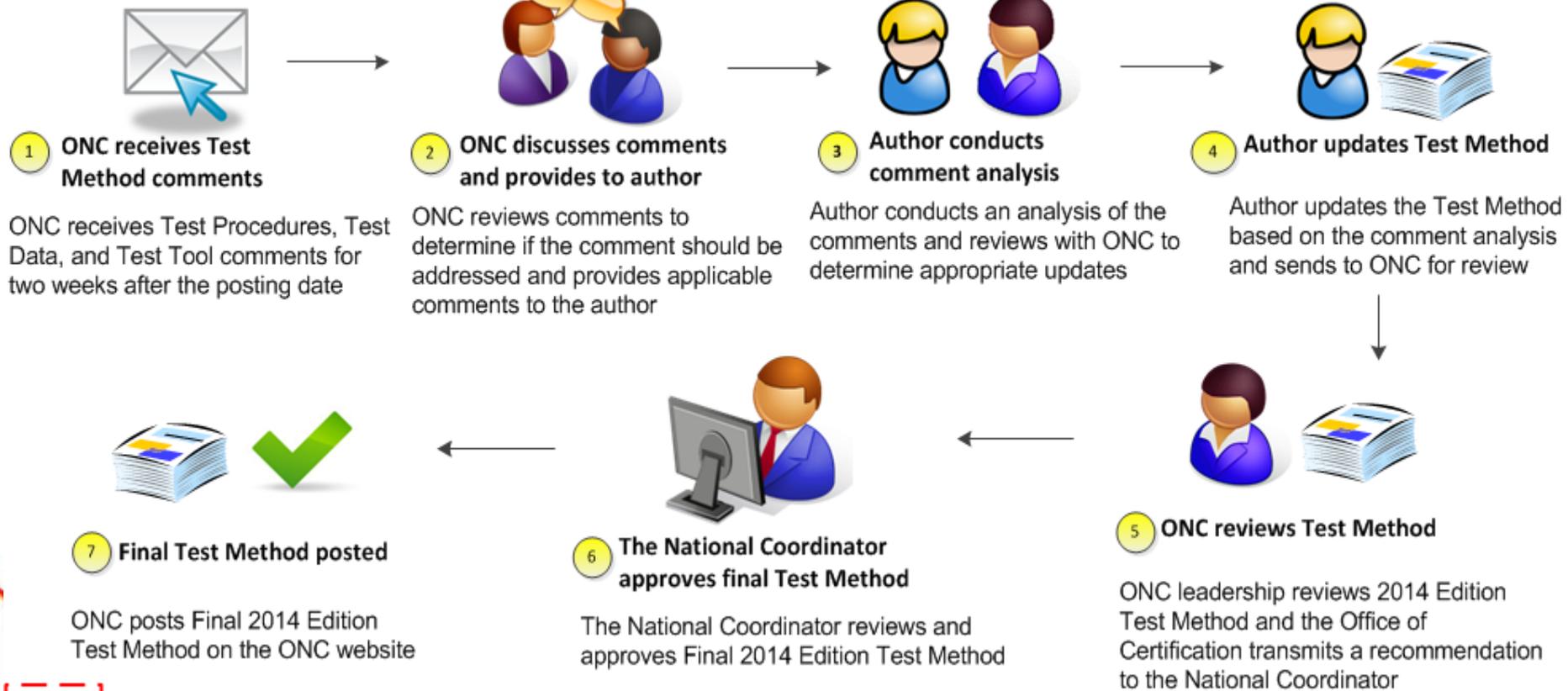


2014 Test Method Review



2014 Test Method Review

START



END



Draft Test Method Review – Wave 1

Wave 1

9/7/12 – 9/21/12

Wave 1 (14 Test Procedures)

- 170.314(a)(1) Computerized provider order entry
- 170.314(a)(4) Vital signs, body mass index, and growth charts
- 170.314(a)(5) Problem list
- 170.314(a)(6) Medication list
- 170.314(a)(7) Medication allergy list
- 170.314(a)(10) Drug formulary checks
- 170.314(a)(11) Smoking status
- 170.314(a)(15) Patient-specific education resources
- 170.314(a)(17) Inpatient setting only—advance directives
- 170.314(d)(5) Automatic log-off
- 170.314(d)(8) Integrity
- 170.314(d)(9) Optional—accounting of disclosures
- 170.314(f)(1) Immunization Information
- 170.314(f)(2) Transmission to immunization registries



Draft Test Method Review – Wave 2

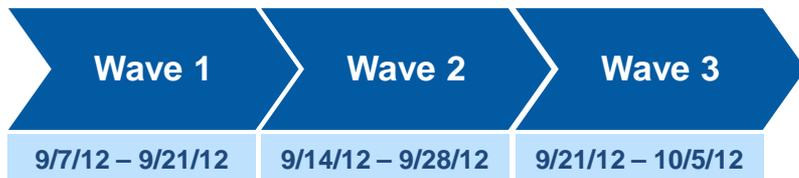


Wave 2 (*7 Test Procedures*)

- 170.314(a)(3) Demographics
- 170.314(a)(9) Electronic notes
- 170.314(a)(13) Family health history
- 170.314(a)(14) Patient list creation
- 170.314(d)(6) Emergency access
- 170.314(f)(5) Ambulatory setting only—cancer case information
- 170.314(f)(6) Ambulatory setting only—transmission to cancer registries



Draft Test Method Review – Wave 3



Wave 3 (6 Test Procedures)

- 170.314(a)(2) Drug-drug, drug-allergy interaction checks
- 170.314(a)(8) Clinical decision support
- 170.314(a)(12) Image Results
- 170.314(a)(16) Inpatient setting only—eMAR
- 170.314(b)(4) Clinical information reconciliation
- 170.314(e)(2) Ambulatory setting only—clinical summary



Draft Test Method Review – Wave 4

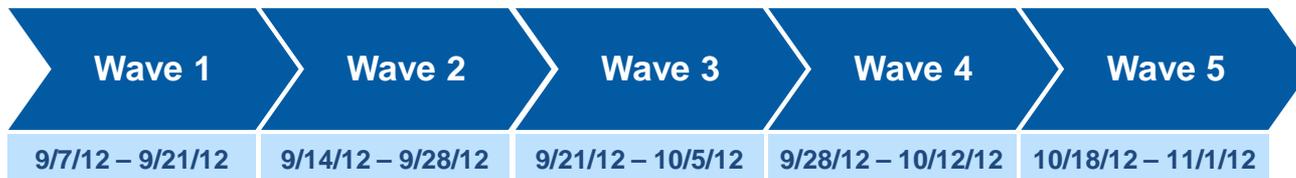


Wave 4 (9 Test Procedures)

- 170.314(b)(7) Data portability
- 170.314(d)(1) Authentication, access control, and authorization
- 170.314(d)(2) Auditable events and tamper-resistance
- 170.314(d)(3) Audit reports
- 170.314(d)(4) Amendments
- 170.314(d)(7) End-user device encryption
- 170.314(e)(3) Ambulatory setting only—secure messaging
- 170.314(f)(3) Transmission to public health agencies—syndromic surveillance
- 170.314(g)(3) Safety-enhanced design



Draft Test Method Review – Wave 5



Wave 5 (4 Test Procedures)

- 170.314(b)(2) Transitions of care—create and transmit transition of care/referral summaries
- 170.314(b)(3) Electronic prescribing
- 170.314(e)(1) View, download, and transmit to 3rd party
- 170.314(f)(4) Inpatient setting only—transmission of reportable lab tests and values/results



Draft Test Method Review – Wave 6



Wave 6 (5 Test Procedures*)

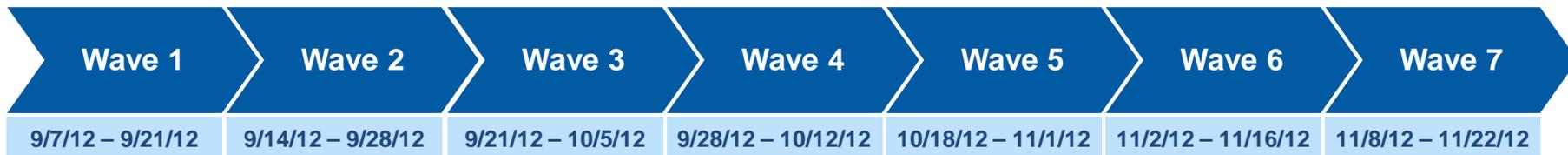
- 170.314(c)(1) Clinical quality measures—capture and export
- 170.314(c)(2) Clinical quality measures—import and calculate
- 170.314(c)(3) Clinical quality measures—electronic submission
- 170.314(g)(1) Automated numerator recording
- 170.314(g)(2) Automated measure calculation

*Drafts are combined into 2 test procedures:

- Clinical quality measures; and
- Automated numerator recording and automated measure calculation



Draft Test Method Review – Wave 7



Wave 7 (4 Test Procedures)

- 170.314(b)(1) Transitions of care—receive, display, and incorporate summary care records
- 170.314(b)(5) Incorporate lab tests and values/results
- 170.314(b)(6) Inpatient setting only—transmission of e-lab test and values/results to Amb provider
- 170.314(g)(4) Quality management system



2014 Edition Test Tools

HL7 v2 Immunization
Information System
(IIS) Reporting Validation Tool

HL7 CDA Cancer Registry
Reporting Validation Tool

HL7 v2 Syndromic Surveillance
Reporting Validation Tool

HL7 v2 Electronic Laboratory
Reporting (ELR) Validation Tool

ePrescribing Validation Tool

HL7 v2 Laboratory Results
Interface (LRI) Validation Tool

Direct Certificate Discovery Tool
(DCDT)

Transport Testing Tool
(includes C-CDA, Direct, and
SOAP)

Cypress Tool

2014 Edition Test Tools – Immunization Information System (IIS)



HL7 v2 Immunization Information System (IIS) Reporting Validation Tool

HL7 CDA Cancer Registry Reporting Validation Tool

HL7 v2 Syndromic Surveillance Reporting Validation Tool

HL7 v2 Electronic Laboratory Reporting (ELR) Validation Tool

ePrescribing Validation Tool

HL7 v2 Laboratory Results Interface (LRI) Validation Tool

Direct Certificate Discovery Tool (DCDT)

Transport Testing Tool (includes C-CDA, Direct, and SOAP)

Cypress Tool

HL7 v2 Immunization Information System (IIS) Validation Tool is used to test the following Certification Criterion:

- 170.314(f)(2) Transmission to immunization registries

2014 Edition Test Tools – Cancer Registry Reporting



HL7 v2 Immunization Information System (IIS) Reporting Validation Tool

HL7 CDA Cancer Registry Reporting Validation Tool

HL7 v2 Syndromic Surveillance Reporting Validation Tool

HL7 v2 Electronic Laboratory Reporting (ELR) Validation Tool

ePrescribing Validation Tool

HL7 v2 Laboratory Results Interface (LRI) Validation Tool

Direct Certificate Discovery Tool (DCDT)

Transport Testing Tool (includes C-CDA, Direct, and SOAP)

Cypress Tool

HL7 CDA Cancer Registry Reporting Validation Tool is used to test the following Certification Criterion:

- (f)(6) Amb. setting only—transmission to cancer registries



2014 Edition Test Tools – Syndromic Surveillance Reporting

HL7 v2 Immunization Information System (IIS) Reporting Validation Tool

HL7 CDA Cancer Registry Reporting Validation Tool

HL7 v2 Syndromic Surveillance Reporting Validation Tool

HL7 v2 Electronic Laboratory Reporting (ELR) Validation Tool

ePrescribing Validation Tool

HL7 v2 Laboratory Results Interface (LRI) Validation Tool

Direct Certificate Discovery Tool (DCDT)

Transport Testing Tool (includes C-CDA, Direct, and SOAP)

Cypress Tool

HL7 v2 Syndromic Surveillance Reporting Validation Tool is used to test the following Certification Criterion:

- 170.314(f)(3) Transmission to public health agencies – syndromic health



2014 Edition Test Tools – Electronic Laboratory Reporting

HL7 v2 Immunization Information System (IIS) Reporting Validation Tool

HL7 CDA Cancer Registry Reporting Validation Tool

HL7 v2 Syndromic Surveillance Reporting Validation Tool

HL7 v2 Electronic Laboratory Reporting (ELR) Validation Tool

ePrescribing Validation Tool

HL7 v2 Laboratory Results Interface (LRI) Validation Tool

Direct Certificate Discovery Tool (DCDT)

Transport Testing Tool (includes C-CDA, Direct, and SOAP)

Cypress Tool

HL7 v2 Electronic Laboratory Reporting (ELR) Validation Tool is used to test the following Certification Criterion:

- 170.314(f)(4) Inp. setting only – transmission of reportable lab tests and values/results



2014 Edition Test Tools – ePrescribing

HL7 v2 Immunization
Information System
(IIS) Reporting Validation Tool

HL7 CDA Cancer Registry
Reporting Validation Tool

HL7 v2 Syndromic Surveillance
Reporting Validation Tool

HL7 v2 Electronic Laboratory
Reporting (ELR) Validation Tool

ePrescribing Validation Tool

HL7 v2 Laboratory Results
Interface (LRI) Validation Tool

Direct Certificate Discovery Tool
(DCDT)

Transport Testing Tool
(includes C-CDA, Direct, and
SOAP)

Cypress Tool

ePrescribing Validation Tool is used to test the following Certification Criterion:

- 170.314(b)(3) Electronic prescribing



2014 Edition Test Tools – Laboratory Results Interface (LRI)

HL7 v2 Immunization Information System (IIS) Reporting Validation Tool

HL7 CDA Cancer Registry Reporting Validation Tool

HL7 v2 Syndromic Surveillance Reporting Validation Tool

HL7 v2 Electronic Laboratory Reporting (ELR) Validation Tool

ePrescribing Validation Tool

HL7 v2 Laboratory Results Interface (LRI) Validation Tool

Direct Certificate Discovery Tool (DCDT)

Transport Testing Tool (includes C-CDA, Direct, and SOAP)

Cypress Tool

HL7 v2 Laboratory Results Interface (LRI) Validation Tool is used to test the following Certification Criteria:

- 170.314(b)(5) Incorporate lab tests and values/results
- 170.314(b)(6) Inp. setting only—trans. of e-lab test and values/results to Amb provider



2014 Edition Test Tools – Direct Certificate Discovery

HL7 v2 Immunization Information System (IIS) Reporting Validation Tool

HL7 CDA Cancer Registry Reporting Validation Tool

HL7 v2 Syndromic Surveillance Reporting Validation Tool

HL7 v2 Electronic Laboratory Reporting (ELR) Validation Tool

ePrescribing Validation Tool

HL7 v2 Laboratory Results Interface (LRI) Validation Tool

Direct Certificate Discovery Tool (DCDT)

Transport Testing Tool (includes C-CDA, Direct, and SOAP)

Cypress Tool

Direct Certification Discovery Tool (DCDT) is used to test the following Certification Criteria:

- 170.314(b)(1) TOC—receive, display, and incorporate summary care records
- 170.314(b)(2) TOC—create and transmit transition of care/referral summaries
- 170.314(e)(1) View, download, and transmit to 3rd party



2014 Edition Test Tools – Transport

HL7 v2 Immunization Information System (IIS) Reporting Validation Tool

HL7 CDA Cancer Registry Reporting Validation Tool

HL7 v2 Syndromic Surveillance Reporting Validation Tool

HL7 v2 Electronic Laboratory Reporting (ELR) Validation Tool

ePrescribing Validation Tool

HL7 v2 Laboratory Results Interface (LRI) Validation Tool

Direct Certificate Discovery Tool (DCDT)

**Transport Testing Tool
(includes C-CDA, Direct, and SOAP)**

Cypress Tool

Transport Testing Tool (TTT) is used to test the following Certification Criteria:

- 170.314(b)(1) TOC—receive, display, and incorporate summary care records
- 170.314(b)(2) TOC—create and transmit transition of care/referral summaries
- 170.314(b)(7) Data portability
- 170.314(e)(1) View, download, and transmit to 3rd party
- 170.314(e)(2) Ambulatory setting only—clinical summary



2014 Edition Test Tools – Cypress

HL7 v2 Immunization
Information System
(IIS) Reporting Validation Tool

HL7 CDA Cancer Registry
Reporting Validation Tool

HL7 v2 Syndromic Surveillance
Reporting Validation Tool

HL7 v2 Electronic Laboratory
Reporting (ELR) Validation Tool

ePrescribing Validation Tool

HL7 v2 Laboratory Results
Interface (LRI) Validation Tool

Direct Certificate Discovery Tool
(DCDT)

Transport Testing Tool
(includes C-CDA, Direct, and
SOAP)

Cypress Tool

Cypress Tool is used to test the following Certification Criteria:

- 170.314(c)(1) Clinical quality measures—capture and export
- 170.314(c)(2) Clinical quality measures—import and calculate
- 170.314(c)(3) Clinical quality measures—electronic submission



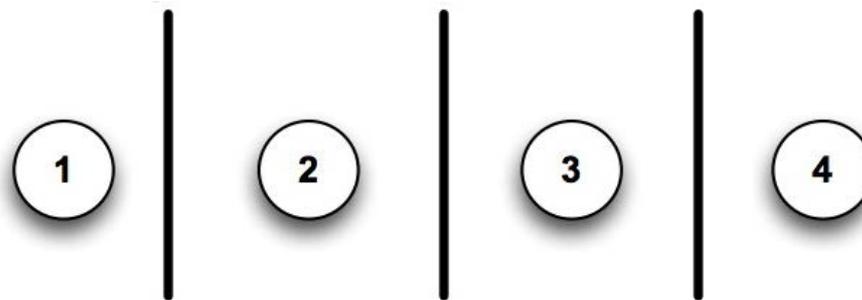
2014 Test Scenarios

Test Scenario Development – Unit Based Testing



- Minimum requirement
- Independent tests
- Individual test data and results
- Currently employed for 2011 Edition Test Procedures

Unit Based Testing

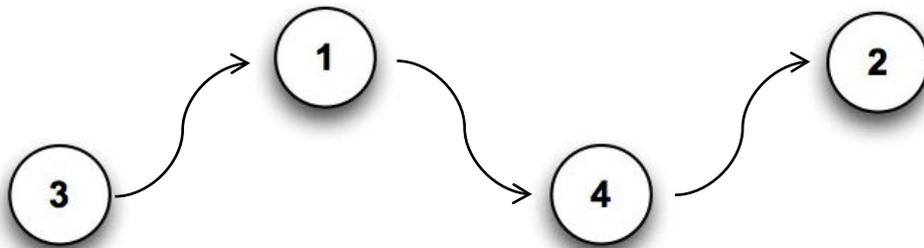


Test Scenario Development – Scenario Based Testing



- Alternative to unit based testing
- Dependent tests
- Dependent test data and results
- Can remove individual test from sequence

Scenario Based Testing



If test 1 is not applicable...





Test Scenario Development – Approach

Approach

- Reflects a typical clinical workflow in multiple care settings
- Allows persistence of data elements (i.e. model for data threading)
- Maintains testing flexibility (e.g. add/remove “unit test”)

Process

Types



Test Scenario Development – Process

Approach

- Reflects a typical clinical workflow in multiple care settings
- Allows persistence of data elements (i.e. model for data threading)
- Maintains testing flexibility (e.g. add/remove “unit test”)

Process

- Develop clinically plausible workflow
- Initial development based on 2011 Edition Certification Criteria
- Reevaluate against the 2014 Edition Certification Criteria

Types



Test Scenario Development – Types

Approach

- Reflects a typical clinical workflow in multiple care settings
- Allows persistence of data elements (i.e. model for data threading)
- Maintains testing flexibility (e.g. add/remove “unit test”)

Process

- Develop clinically plausible workflow
- Initial development based on 2011 Edition Certification Criteria
- Reevaluate against the 2014 Edition Certification Criteria

Types

- Medication Management
- Emergency Department
- Interoperability
- Outpatient
- Inpatient



Program & Test Method Conclusion

ONC HIT Certification Program

- ONC launched the ONC HIT Certification Program on October 4, 2012
- Includes new name and structure
- Separate entities for testing and certification

CHPL

- ONC is currently developing CHPL 3.0
- Ability to download 'CHPL Product Information'

Test Method

- Includes 2014 Ed. Test Procedures, Test Data, and Test Tools
- Draft Test Method currently undergoing review
- Final Test Method posted in mid-December 2012



2014 Test Method

Certification Criteria – Changes from 2011 to 2014 Edition



New

Revised

Unchanged
(w/ and w/o refinements)

Factors considered to determine whether a certification criteria is “new”:

- The certification criterion only specifies capabilities that have never been included in previously adopted certification criteria; or
- The certification criterion was previously adopted as “mandatory” for a particular setting and subsequently adopted as “mandatory” or “optional” for a different setting.

Certification Criteria – Changes from 2011 to 2014 Edition



New

Revised

Unchanged
(w/ and w/o refinements)

Factors considered to determine whether a certification criteria is “revised”:

- The certification criterion includes changes to capabilities that were specified in the previously adopted certification criterion;
- The certification criterion has a new mandatory capability that was not included in the previously adopted certification criterion; or
- The certification criterion was previously adopted as “optional” for a particular setting and is subsequently adopted as “mandatory” for that setting.

Certification Criteria – Changes from 2011 to 2014 Edition



New

Revised

Unchanged
(w/ and w/o refinements)

Factors considered to determine whether a certification criteria is “unchanged”:

- The certification criterion includes only the same capabilities that were specified in previously adopted certification criteria;
- The certification criterion’s capabilities apply to the same setting as they did in previously adopted certification criteria; and
- 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.



Draft Test Method Review – Wave 1

Wave 1

9/7/12 – 9/21/12

Wave 1 (14 Test Procedures)

Unchanged without Refinements

- 170.314(a)(6) Medication list
- 170.314(a)(7) Medication allergy list
- 170.314(a)(17) Inpt. setting only—Advance directives
- 170.314(d)(9) Optional—Accounting of disclosures

Unchanged with Refinements

- 170.314(a)(1) Computerized provider order entry
- 170.314(d)(5) Automatic log-off
- 170.314(d)(8) Integrity

Revised

- 170.314(a)(4) Vital signs, body mass index, and growth charts
- 170.314(a)(5) Problem list
- 170.314(a)(10) Drug formulary checks
- 170.314(a)(11) Smoking status
- 170.314(a)(15) Patient-specific education resources
- 170.314(f)(1) Immunization Information
- 170.314(f)(2) Transmission to immunization registries

11/13/2012



Cert. Criterion

Medication List. Enable a user to electronically record, change, and access a patient’s active medication list as well as medication history:

- i. Ambulatory setting. Over multiple encounters; or
- ii. Inpatient setting. For the duration of an entire hospitalization.

TP Components

Record – evaluates the capability to enter patient active med data into the EHR to create the patient active med list
Change – evaluates the capability to change patient med data that have been previously entered into the EHR
Access – evaluates the capability to display the patient med list data that have been previously entered into the EHR, including the capability to display the patient med list as recorded during multiple ambulatory encounters with the same provider or during the duration of an entire inpatient hospitalization

Public Review Summary

Test Procedure Comments

- Clarify how to reconcile medications entered during multiple encounters.

Test Data Comments

- Clarify whether the list of “all medications including those that have been discontinued” must be one centralized list.
- Clarify that RxNorm codes are provided for reference.



Cert. Criterion

Medication Allergy List. Enable a user to electronically record, change, and access a patient’s active medication allergy list as well as medication allergy history:

- i. Ambulatory setting. Over multiple encounters; or
- ii. Inpatient setting. For the duration of an entire hospitalization.

TP Components

Record – evaluates the capability to enter patient active med allergy data into the EHR to create the patient active med allergy list

Change – evaluates the capability to change patient med allergy data that have been previously entered into the EHR

Access – evaluates the capability to display the patient med allergy list data that have been previously entered into the EHR, including the capability to display the patient med allergy list as recorded during multiple ambulatory encounters with the same provider or during the duration of an entire inpatient hospitalization

Public Review Summary

Test Procedure Comments

- Clarify how to reconcile medication allergies entered during multiple encounters.

Test Data Comments

- Clarify that RxNorm codes are provided for reference.
- Criterion itself does not specify the data elements that must be recorded, changed, or accessed; however, we recognize the elements contained in the test data reflect current industry practices. Consider clarifying.
- Clarify whether the list of “all medication allergies including those that have been discontinued” must be one centralized list.
- To what level of specificity within the RxNorm hierarchy should the user be able to select a medication for identifying allergies?



Cert. Criterion

Inpatient setting only – Advance directives. Enable a user to electronically record whether a patient has an advance directive.

TP Components

Record – evaluates the capability to enter into the EHR whether a patient has an advance directive

Public Review Summary

Test Procedure Comments

- No comment



Cert. Criterion

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

TP Components

Record Disclosures – evaluates the capability to enter treatment, payment, and health care operations disclosures into the EHR

Public Review Summary

Test Procedure Comments

- No comment



Cert. Criterion

Computerized provider order entry. Enable a user to electronically record, change, and access the following order types, at a minimum:

- i. Medications;
- ii. Laboratory; and
- iii. Radiology/imaging.

TP Components

Record - evaluates the capability to electronically enter orders for medications, laboratory, and radiology/imaging within the EHR system

Change - evaluates the capability for a user to electronically change entered orders for medications, laboratory, and radiology/imaging in the EHR

Access - evaluates the capability to access and display the orders that have been previously entered into the EHR

Public Review Summary

Test Procedure Comments

- In an ambulatory setting, medications are “prescribed” not “ordered”.
- Since the test procedures for ambulatory and inpatient are identical, consider combining into three sections (Record, Change, and Access) and then indicate which setting specific test data to use for each step.
- Different laboratory and radiology/imaging orders have completely different charge codes. Instead of “changing” orders, consider “cancelling” the order and submitting a new order.

Test Data Comments

- Renumber the inpatient data sets to align with the test procedure.
- Clarify abbreviations by spelling out.
- Consider using Joint Commission standard pertaining to ambiguous abbreviations (e.g. “daily” instead of “QD”).
- Consider listing medications by generic name instead of trade/brand name.
- Ensure that orders are appropriate for the setting.
- Consider adding RxNorm codes as reference.



Cert. Criterion

Automatic log-off. Prevent a user from gaining further access to an electronic session after a predetermined time of inactivity.

TP Components

Prevent a User from Gaining Further Access to an Electronic Session – evaluates the capability to prevent a user from gaining further access to an electronic session after a predetermined time of inactivity

Public Review Summary

Test Procedure Comments

- Clarify if it is acceptable for the limit access functionality to be accomplished by a 3rd party or OS-level solution.
- Clarify the distinction between “terminate” and “lock” to make the test procedure clearer.



Integrity.

- i. Create a message digest in accordance with the standard specified in §170.210(c).
- ii. Verify in accordance with the standard specified in §170.210(c) upon receipt of electronically exchanged health information that such information has not been altered.

Create Hash Values – evaluates the capability to create a hash value

Compare Hash Values – evaluates the capability to compare hash values to ensure the electronic health information has not been altered in transit

Create, Exchange, and Verify – evaluates the capability to create a hash of health information in accordance with the standard specified in 170.210(c), electronically exchange the health information and the created message digest to a receiving system, and verify that the electronically exchanged health information has not been altered

Test Procedure Comments

- Consider recommendations for transporting the hashed health information.
- Suggest that there be a test step to ensure the file/data being hashed is in some way tied/associated to the hash value.
- Clarify whether the use of a 3rd party tool to generate a hash values satisfies the testing requirements.



Cert. Criterion

Vital signs, body mass index, and growth charts.

- i. Vital signs. Enable a user to electronically record, change, and access, at a minimum, a patient's height/length, weight, and blood pressure. Height/length, weight, and blood pressure must be recorded in numerical values only.
- ii. Calculate body mass index. Automatically calculate and electronically display body mass index based on a patient's height and weight.
- iii. Optional – Plot and display growth charts. Plot and electronically display, upon request, growth charts for patients.

TP Components

Vital signs

Record - evaluates the capability to enter vital signs data into the EHR system in numerical values only

Change – evaluates the capability to change vital signs data that have been entered previously into the EHR

Access – evaluates the capability to display the vital signs data that have been entered previously into the EHR

BMI: Calculate and electronically display - evaluates the capability to calculate and electronically display BMI based on a patient's height and weight

Growth charts: Plot and Display - evaluates the capability to plot and electronically display, upon request, growth charts for patients

Public Review Summary

Test Procedure Comments

- Clarify whether gender and age should be displayed on the growth chart or within the patient record.
- Consider allowing numerical vital signs to be recorded with the units in the same field.
- Clarify how many data points should be displayed simultaneously on a growth chart per male and female patient.

Test Data Comments

- For growth chart test data, align ages with meaningful use objective/measure.
- Consider making vital signs and BMI test data the same because EHR technologies automatically calculate the BMI upon entry of the height and weight.
- Consider making growth chart data historical data of a single patient.



Problem list. Enable a user to electronically record, change, and access a patient's active problem list:

- i. Ambulatory setting. Over multiple encounters in accordance with, at a minimum, the version of the standard specified in §170.207(a)(3); or
- ii. Inpatient setting. For the duration of an entire hospitalization in accordance with, at a minimum, the version of the standard specified in §170.207(a)(3).

Record – evaluates the capability to enter patient health problems into the EHR to create the patient active problem list

Change – evaluates the capability to change patient active problem list data which have been previously entered into the EHR

Access – evaluates the capability to display the patient problem list data that have been previously entered into the EHR, including the capability to display the patient problem list as recorded during multiple ambulatory encounters with the same provider or during a single inpatient hospitalization

Test Procedure Comments

- Clarify how to reconcile problems entered during multiple encounters.
- Consider adding a test step that verifies that a diagnosis code matches the problem entered for the manual entry of problem data.
- Clarify what is meant by “and the correct values”.

Test Data Comments

- Consider grouping test data according to dates of an encounter or in a hospital stay.
- Suggest having the exact same number of codes for a vendor to record and change, regardless of whether they are using SNOMED-CT Codes or US Extension Codes.

Cert.
Criterion

Drug-formulary checks. EHR technology must automatically and electronically check whether a drug formulary (or preferred drug list) exists for a given patient and medication.

TP
Components

Check – evaluates the capability for a Complete EHR or EHR Module to automatically and electronically check whether a drug formulary (or preferred drug list) exists for a given patient and medication

Public Review Summary

Test Procedure Comments

- Consider doing positive and negative testing.
- Recommend adding a test step to check for a recommendation of similar drugs that are not on a formulary.

Test Data Comments

- Test data may not allow for positive and negative testing.
- Consider combining the test data into one set to align with the test procedure.
- Clarify that RxNorm codes are provided for reference.

Cert.
Criterion

Smoking status. Enable a user to electronically record, change, and access the smoking status of a patient in accordance with the standard specified at § 170.207(h).

TP
Components

Record – evaluates the capability to enter patient smoking status data

Change – evaluates the capability to change patient smoking status data that have been entered previously into the EHR

Access – evaluates the capability to display the patient smoking status data that have been entered previously into the EHR during the test

Public Review Summary

Test Procedure Comments

- Allow for mapping to the SNOMED codes.
- Clarify mapping to heavy/light tobacco smoker.

Test Data Comments

- Clarify whether displaying SNOMED codes in the interfaces is required.



Cert. Criterion

Patient-specific education resources. EHR technology must be able to electronically identify for a user patient-specific education resources based on data included in the patient's problem list, medication list, and laboratory tests and values/results:

- i. In accordance with the standard specified at § 170.204(b) and the implementation specifications at § 170.204(b)(1) or (2); and
- ii. By any means other than the method specified in paragraph (a)(15)(i) of this section.

TP Components

Identify – evaluates the capability for an EHR Technology to be able to electronically identify for a user patient-specific education resources based on data included in the patient's problem list, medication list, and laboratory tests and values/results:

- i. In accordance with the standard specified at § 170.204(b) and the implementation specifications at § 170.204(b)(1) or (2); and
- ii. By any means other than the method specified in paragraph (a)(15)(i) of this section.

Public Review Summary

Test Procedure Comments

- Clarify that data must automatically and electronically be pulled from the EHR (i.e. does not allow manual entry).
- Clarify why two or more patients are needed for demonstrating compliance to this criterion.
- Clarify evaluation of compliance to the Infobutton standard.
- Clarify that the Infobutton does not allow a user to “select a patient”.
- Consider removing the “provide” step.
- Clarify how “test values/results” will be used in Infobutton.



Immunization information. Enable a user to electronically record, change, and access immunization information.

Record – evaluates the capability for a user to enter immunization information into the EHR

Change – evaluates the capability for a user to change immunization information that has been entered previously into the EHR

Access – evaluates the capability for a user to access the immunization information that has been entered into the EHR

Test Procedure Comments

- In some EHRs, marking an immunization as an error deletes the entry. Thus making it impossible to access in the following step.
- Recommend adding instructions which clearly state that the test procedure is not prescriptive about the method used for changes.
- Is shortening immunization expiration date from MMDDYYYY to MMYYYY acceptable?
- Is vendor expected to retain an electronic copy of the Vaccine Administration Statement given to the patient?
- Test scripts imply documentation of immunizations as “Unknown”. Please clarify whether if this is prescriptive of specific implementation.

Test Data Comments

- Consider aligning test data sets with 170.314(f)(2) Transmission to immunization registries data sets.
- Typo bottom on page 2 – should be “Electronically Access Immunization Information”.
- Test data files starting with "IZ" appear to be ambulatory scenarios. Do these apply to Hospital testing as well?
- The message content data sheet suggests that “immunity” is expressed in SNOMED. Please provide an example.

Cert.
Criterion

Transmission to immunization registries. EHR technology must be able to electronically create immunization information for electronic transmission in accordance with:

- i. The standard and applicable implementation specifications specified in § 170.205(e)(3); and
- ii. At a minimum, the version of the standard specified in § 170.207(e)(2).

TP
Components

Create – evaluates the capability of the EHR technology to electronically generate conformant HL7 messages for immunization information

Public Review Summary

Test Procedure Comments

- Some EHRs send one message per vaccination event rather than a single message containing all vaccinations administered on a day of service, and automatically query the registry when patient records are opened.
- How many test data sets must be entered? Can they be pre-entered?

Test Data/Tool Comments

- Consent test scripts could be more accurate if revised to reflect the fact that some reporting is mandatory.
- What actors in each setting must be captured in the message fields? Can exceptions be made for situations where this data might not be available? With historical vaccines for adults, for instance, Ordering Provider is frequently not available.
- Test data files starting with "IZ" appear to be ambulatory scenarios. Do these apply to Hospital testing as well?
- The message content data sheet suggests that "immunity" is expressed in SNOMED. Please provide an example.



Draft Test Method Review – Wave 2



Wave 2 (7 Test Procedures)

Unchanged
with
Refinements

170.314(d)(6) Emergency access

Revised

170.314(a)(3) Demographics

170.314(a)(14) Patient list creation

New

170.314(a)(9) Electronic notes

170.314(a)(13) Family health history

170.314(f)(5) Amb. setting only—Cancer case information

170.314(f)(6) Amb. setting only—Transmission to cancer registries



Cert. Criterion

Emergency Access. Permit an identified set of users to access electronic health information during an emergency.

TP Components

Assign authorization – evaluates the capability to assign and permit emergency access authorizations and access to electronic health information during an emergency.

Public Review Summary

Test Procedure Comments

- None



Demographics.

- i. Enable a user to electronically record, change, and access patient demographic data including preferred language, sex, race, ethnicity, and date of birth.
 - A. Enable race and ethnicity to be recorded in accordance with the standard specified in § 170.207(f) and whether a patient declines to specify race and/or ethnicity.
 - B. Enable preferred language to be recorded in accordance with the standard specified in § 170.207(g) and whether a patient declines to specify a preferred language
- ii. Inpatient setting only. Enable a user to electronically record, change, and access preliminary cause of death in the event of a mortality.

Record – evaluates the capability for a user to enter patient demographic data into the EHR technology

Change – evaluates the capability for a user to change patient demographic data that were entered into the EHR during the Record test

Access – evaluates the capability for a user to access the patient demographic data that were entered into the EHR during the Record test and Change test

Test Procedure Comments

- Current Normative Test Procedure lacks explicit step to verify more than one race and ethnicity can be recorded, changed, and accessed.
- Current Inspection Test Guide does not verify back-end functionality to record all languages; EHRs must be capable of recording all languages in the ISO standard, but preamble prohibits requiring all languages to be displayed.
- Request to specify how long changes to demographic data should be retained.
- Current Normative Test Procedure lacks explicit step to verify that the term “multiracial” does not appear.

Test Data Comments

- Recommend aligning the ambulatory and inpatient test data.
- Test data should have 1 additional race provided, to comply with the requirement to record 2 races for each patient.



Cert. Criterion

Patient list creation. Enable a user to electronically and dynamically select, sort, access, and create patient lists by: date and time; and based on each one and at least one combination of the following data:

- | | |
|----------------------------|--|
| i. Problems; | iv. Demographics; |
| ii. Medications; | v. Laboratory tests and values/results; and |
| iii. Medication allergies; | vi. <u>Ambulatory setting only</u> . patient communication preferences |

TP Components

Select – evaluates the capability for a user to electronically and dynamically select by date and time
Sort and Access – evaluates the capability for a user to electronically and dynamically 1) access lists of patients that are selected based on date and time and the Vendor-supplied test data for the data elements included in the Problem list, Medication list, Medication Allergy list, Demographics, Laboratory tests and values/results, and, in the ambulatory setting only, patient communication preferences, and 2) sequence or arrange the data on each patient list using the date and time and those data elements

Public Review Summary

Test Procedure Comments

- Current Test Procedure lacks clarity and step(s) to verify that select/sort/access/create functions are done “dynamically”.
- Request for clarification on which dates and times are required or to use only when relevant because many possible dates and times exist in relation to patient data (e.g. date of last test, date of last visit, date of onset of a problem, date when medication started, date that criteria was met).
- Request for clarification on whether “date and time” testing data is vendor supplied.
- Request for confirmation that “communication preferences” is limited to the ambulatory setting only and must be used to select, sort, access, and create a patient list.
- Comments did not address material that was testable or related to testing methodology.
- Clarify that DTR170.314.a.14-6 requires the previous lists to be used as input to the creation of a third new list.
- Test procedure requires creation of more lists than the 2011 Edition criteria and asked that vendors be able to display two or more data elements within one list.
- Request to re-sequences the test requirements to place “Create” before “Sort and Access”.



Electronic notes. Enable a user to electronically record, change, access, and search electronic notes.

Record - evaluates the capability for a user to enter electronic notes into the EHR

Change - evaluates the capability for a user to change electronic notes that have been entered previously into the EHR

Access - evaluates the capability for a user to access electronic notes that have been entered previously into the EHR

Search - evaluates the capability for a user to search within an electronic note that is stored in the patient's EHR

Test Procedure Comments

- Include negative test data to align with test procedure.
- Use of vendor-supplied data.
- Request to clarify if note needs to be signed, unsigned. CMS sys it needs to be a signed note.
- Feedback addressed objective and not testing methodology.
- Capability to search within vs. across notes.
- Search functionality in EHR vs. web-based.

Test Data Comments

- Clarify if the Vendor is responsible for showing the strikethrough during the testing procedure.
- Recommend removing Test Data 3 because in the "Change" section, the note is deleted; thus, making it impossible to "Search" in the next section. Tester cannot use this data set for the whole test.
- Recommend removing "1st" and "2nd" from the search statements to remove confusion.



Cert. Criterion

Family health history. Enable a user to electronically record, change, and access a patient's family health history according to:

- i. At a minimum, the version of the standard specified in § 170.207(a)(3); or
- ii. The standard specified in § 170.207(j).

TP Components

Record – evaluates the capability for a user to enter a patient's family health history data into the EHR

Change – evaluates the capability for a user to change a patient's family health history data that have been entered previously into the EHR

Access – evaluates the capability for a user to access a patient's family health history data that have been entered previously into the EHR

Public Review Summary

Test Procedure Comments

- Specificity of vendor-supplied test data to demonstrate family relationships and specific health conditions.
- Minimum set of family health history of data points to interpret “inclusive of parents, offspring, and siblings.”
- Test Procedure categorized as “new” and not “revised”.
- HL7 as an Exchange standard and SNOMED CT as a vocab standard: “There's never any inspection as to whether the information is ever exchanged using the CG Pedigree Interactions or Messages.”
- Standards compliance testing without a test tool: distinction between required test data elements in conformance with standards and test data as unstructured data.
- First degree relatives included in broader family health history vs. capability to filter first degree relatives separately.



New

§170.314(f)(5) Amb. setting only – Cancer case information

Cert.
Criterion

Ambulatory setting only—cancer case information. Enable a user to electronically record, change, and access cancer case information

TP Components

Record – evaluates the capability for a user to enter cancer case information into the EHR

Change – evaluates the capability for a user to change cancer case information that has been entered previously into the EHR

Access – evaluates the capability for a user to access the cancer case information that has been entered into the EHR

Public Review Summary

Test Procedure Comments

- None

Test Data: CNC-supplied

Test Tool: None

Standards: None

Cert.
Criterion

Optional---ambulatory setting only—transmission to cancer registries. EHR technology must be able to electronically create cancer case information for electronic transmission in accordance with:

- i. The standard (and applicable implementation specifications) specified in § 170.205(i); and
- ii. At a minimum, the versions of the standards specified in § 170.207(a)(3) and (c)(2)..

TP
Components

Create – evaluates the capability of the EHR technology to electronically create conformant standard reports for cancer case information

Public Review Summary

Test Procedure Comments

- For the public health testing where multiple Test Cases and randomly-selected Data Sets for each Test Case must be input for set-up of each EHR system for the certification testing, can the ATLS indicate to the vendor which data sets will be tested before the inspection, so the vendor is only pre-entering, for example, 7 sets of data instead of 21 sets of data?

Test Data Comments

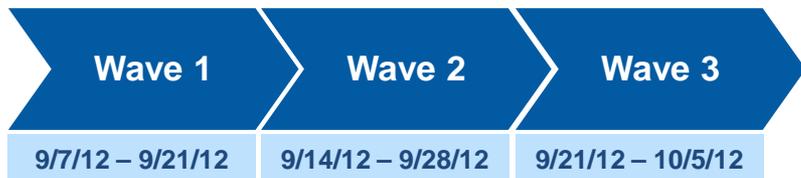
- “For all instances where a Change action is listed, we suggest sequencing the [test data] modifications in the same order that the items were entered during the Record portion of the test. For example, in the CPOE test data document, Page 5, Data Set 1, placing the Famotidine modification above Diazepam would ensure that the changes occur in the same sequence the medications were ordered.”
- Immunization registries TP, C-CDA TPs, e-Prescribing TP, and quality measures TPs have 2-3 different vocabulary requirements for Route of Administration. Consider harmonizing the vocabularies to converge upon a single value set.

Test Tool Comments

- None



Draft Test Method Review – Wave 3



Wave 3 (6 Test Procedures)

Revised	170.314(a)(2)	Drug-drug, drug-allergy interaction checks
	170.314(a)(8)	Clinical decision support
	170.314(b)(4)	Clinical information reconciliation
	170.314(e)(2)	Amb. setting only—Clinical summary
New	170.314(a)(12)	Image results
	170.314(a)(16)	Inpt. setting only—eMAR



Drug-drug, drug-allergy interaction checks

- i. Interventions. Before a medication order is completed and acted upon during computerized provider order entry (CPOE), interventions must automatically and electronically indicate to a user drug-drug and drug-allergy contraindications based on a patient's medication list and medication allergy list.
- ii. Adjustments.
 - A. Enable the severity level of interventions provided for drug-drug interaction checks to be adjusted.
 - B. Limit the ability to adjust severity levels to an identified set of users or available as a system administrative function.

Indicate – evaluates the capability for the EHR to indicate interventions for drug-drug and drug-allergy contraindications, based on a patient's medication list and medication allergy list, automatically and electronically to the user during CPOE before an order is completed and acted upon.

Adjust and limit – evaluates the capability for an identified limited set of users to make adjustments to the severity level of interventions provided for drug-drug interaction checking.

Test Procedure Comments

- Request that CPOE not be required to meet compliance to this procedure.
- Clarify “high significance” and “low significance”.
- Clarify references to licensed professional, user with “ability to adjust”, and user with “ability to place orders”.
- Clarify whether the user should select an icon/button in order to display an intervention or whether the intervention should display automatically.
- Suggest that DTR170.314.a.2 – 1 be eliminated due to redundancy with 2.04-2.08 (severity level).



Cert. Criterion

Clinical decision support.

- i. Evidence-based decision support interventions. Enable a limited set of identified users to select (i.e., activate) one or more electronic clinical decision support interventions (in addition to drug-drug and drug-allergy contraindication checking) based on each one and at least one combination of the following data...
- ii. Linked referential clinical decision support...
- iii. Clinical decision support configuration...
- iv. Automatically and electronically interact. Interventions triggered in accordance with paragraphs (a)(8)(i) through (iii) of this section must automatically and electronically occur when a user is interacting with EHR technology...
- v. Source attributes. Enable a user to review the attributes as indicated for all clinical decision support resources:..

TP Components

Select/Activate – evaluates the capability for a limited set of identified users to select (i.e., activate) one or more electronic clinical decision support interventions (in addition to drug-drug and drug-allergy contraindication checking) in the EHR technology based on data from each one and at least one combination of data from two or more of the following data categories:

Trigger – evaluates the capability for the EHR technology to electronically trigger interventions

Occur – evaluates the capability of clinical decision support interventions, triggered based on the capabilities and data elements listed above, to occur automatically and electronically when a user is interacting with the EHR technology

Identify – evaluates the capability for the EHR technology to electronically identify for a clinical user the diagnostic and therapeutic reference information based on data from each one and at least one combination of data from two or more of the following data categories:

Configure – evaluates the capability of a limited set of identified users to configure clinical decision support interventions and diagnostic and therapeutic reference resources into the EHR technology based on the user's clinical role.

Review – evaluates the capability of the EHR technology to enable a user to review the following information for evidence-based clinical decision support interventions associated with data in the Problem list, Medication list, Medication allergy list, Demographics, Laboratory tests and values/results, and Vital signs:

Review – evaluates the capability of the EHR technology to enable a user to review the following information for diagnostic and therapeutic reference resources associated with data in the Problem list, Medication list, Medication allergy list, Demographics, Laboratory tests and values/results, and Vital signs:

Review – evaluates the capability of the EHR technology to enable a user to review the following information for drug-drug and drug-allergy interaction checks (specified in the ONC EHR certification criterion 170.314.a.2 Drug-drug, drug-allergy interaction checks)

Public Review Summary

Test Procedure Comments

- Suggest that demographics and vitals should only be modifiers for other triggers of CDS and should not trigger CDS independently
- Request that required testing reflect current HL7 capabilities and that additional HL7 language be added to the test procedure
- Request for confirmation that separate testing of 314(b)(5) "Incorporate Lab Test and Values/Results" is not required.
- Request for confirmation that CDA data should be integrated real-time.
- Request for guidance regarding how many CDS interventions are required for verification.
- Request that "at least" be removed from test procedure language and that steps be re-ordered.
- Requirement does not seem to appear explicitly in the test/script.
- Request that the difference between "select/activate" and "configure" be further clarified.
- Request mapping of "Developer", "Funding Source", and "Revision Dates".
- Clarify one must also test and certify to 170.314(b)(1) and whether there is an additional requirement in the Ambulatory domain to test and certify 170.314(b)(5).
- Suggest removing the last TE statement with reference to the IN.
- Clarify why users of different roles are being used and whether or not all testing data can come from a single CCDA.
- Clarify whether it is acceptable that the EHR "hard codes" certain CDS interventions into its architecture.



- Clinical information reconciliation.** Enable a user to electronically reconcile the data that represent a patient's active medication, problem, and medication allergy list as follows. For each list type:
- i. Electronically and simultaneously display (i.e., in a single view) the data from at least two list sources in a manner that allows a user to view the data and their attributes, which must include, at a minimum, the source and last modification date.
 - ii. Enable a user to create a single reconciled list of medications, medication allergies, or problems.
 - iii. Enable a user to review and validate the accuracy of a final set of data and, upon a user's confirmation, automatically update the list.

Reconcile – evaluates the capability for a user to electronically create a single reconciled list of data elements in a patient's active medication list, a patient's active problem list, and a patient's active medication allergy list

Test Procedure Comments

- Request that Vendor can choose display of merged list before it is submitted and becomes the active medication list.
- Clarify how and from where to extract last modification date from the various lists.
- Request additional language explicitly stating that reconciliation is not meant to occur through one step.
- Request that "at least" be removed from test procedure language and clarify labeling data as "external".
- Suggest adding a step to verify the patient identity.
- Request that a patient record be created prior to the start of the test for testing efficiency.
- Clarify the ability to remove a medication simply by not selecting it during the consolidation step.
- Clarify that one list for each can be the active list for problems, medications, and medication allergies.
- Clarify ability to remove problems, medication, or medication allergies from the active list.

Test Data Comments

- Remove all listed dates other than modification date.
- Clarify if "additional list" data is vendor-supplied.
- Suggest modifying problem and medication allergy list test data.
- No referenced standards; however, test data includes coded data.



Ambulatory setting only – clinical summary

- i. Create. Create. Enable a user to create a clinical summary for a patient in human readable format and formatted according to the standards adopted at § 170.205(a)(3).
- ii. Customization. Enable a user to customize the data included in the clinical summary.
- iii. Minimum data from which to select. EHR technology must permit a user to select, at a minimum, the following data when creating a clinical summary: ...

Create – evaluates the capability for the EHR technology to enable a user to generate a clinical summary for a patient in human readable format and according to the Implementation Guide for CDA® Release 2.0, Consolidated CDA Templates; and including, at a minimum, the provider's name and office contact information; date and location of visit; reason for visit; immunizations and/or medications administered during the visit; diagnostic tests pending; clinical instructions; future appointments; referrals to other providers; future scheduled tests; recommended patient decision aids; and the Common MU Data Set data with named standards as appropriate (in their English representation if they associate with a vocabulary/code set).

Customize – evaluates the capability for a user to customize the data included in the clinical summary

Test Procedure Comments

- Define and clarify scope of customizing clinical summaries, including requirement to delete and/or add information.
- Clarify the Test Procedure follows the certification criteria language in requiring “and/or” (not “and”).
- Clarify definition for “assessment” and its rule in a C-CDA.
- Clarify if future tests in Care Plan, role of smoking status history in C-CDA, and role of family health history in C-CDA.
- Suggest repeat test data steps for inclusion/exclusion of data elements and addressing formatting (spelling, code verification...).
- Clarify and expand test step to display human readable and provide as an outputted data message.
- Clarify expected response to errors, warnings, or information messages from the C-CDA conformance tool.

Test Data Comments

- Clarify if all the course vocabularies contained in RxNorm are permitted.
- Suggest inclusion of LOINC codes for labs and CPT codes for procedures.
- Clarify that historical data is not required in clinical summary (e.g., vital signs).
- Request vendor-supplied test data.

Test Tool Comments

- Clarify and add instruction regarding import of C-CDA into conformance tool for validation.

Cert.
Criterion

Image results. Electronically indicate to a user the availability of a patient's images and narrative interpretations (relating to the radiographic or other diagnostic test(s)) and enable electronic access to such images and narrative interpretations.

TP
Components

Indicate – evaluates the capability for the EHR to electronically indicate to a user the availability of a patient's images and associated narrative interpretations relating to radiographic or other diagnostic test(s)
Access – evaluates the capability for the user to electronically access and display the patient's images and narrative interpretations

Public Review Summary

Test Procedure Comments

- Clarify basis for validating accuracy and completeness of an image when source system is out of scope and test data is vendor-supplied.
- Request additional relevant preamble quotes to address removal of “immediate access” from criterion vs. TP requirement of access without additional provider login and patient lookup/selection.
- Request to include narrative interpretations in image testing per the regulation text.
- Clarify acceptability of storage location of images and narratives (narrative in EHR and image external, both external, both internal, etc.).
- Suggest inclusion and placement of “other diagnostic tests”.
- Suggest modification of testing sequence to ensure test of adding an image that was not previously in the EHR.
- Suggest inclusion of sample test data.



Inpatient setting only—electronic medication administration record.

- 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):
 - 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.

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

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

Test Procedure Comments

- For testing the ability of the eMAR to determine the “wrong time,” confirm that the vendor would generate or create, on their own, the “compliant parameters” for this test.
- Clarify if mix of automates and manual functionalities would apply.
- Clarify if the EHR must query the NTP servers directly.
- Clarify if internal NTP servers are permitted.
- Clarify if manual entry is an insufficient method of demonstrating compliance with this criterion.

Test Data Comments

- Patient name should be vendor-supplied.
- Clarify the information within the parenthesis to remove confusion.



Draft Test Method Review – Wave 4



Wave 4 (9 Test Procedures)

Unchanged
with
Refinements

170.314(d)(1) Authentication, access control, and authorization

Revised

170.314(d)(2) Auditable events and tamper-resistance

170.314(d)(3) Audit reports

170.314(d)(7) End-user device encryption

170.314(f)(3) Transmission to public health agencies—syndromic surveillance

New

170.314(b)(7) Data portability

170.314(d)(4) Amendments

170.314(e)(3) Amb. setting only—Secure messaging

170.314(g)(3) Safety-enhanced design



Cert. Criterion

Authentication, access control, and authorization.

- i. Verify against a unique identifier(s) (e.g., username or number) that a person seeking access to electronic health information is the one claimed; and
- ii. Establish the type of access to electronic health information a user is permitted based on the unique identifier(s) provided in paragraph (d)(1)(i) of this section, and the actions the user is permitted to perform with the EHR technology.

TP Components

Authenticate Unique User— evaluates the capability of the EHR technology to establish the identification and authentication information associated with a unique user identifier.

Establish Permitted User Access— evaluates the capability of the EHR technology to establish permitted access to electronic health information and to permit authorized actions within the EHR technology

Public Review Summary

Test Procedure Comments

- Request to add test step to require Tester to log in with incorrect credentials
- Request to add requirements for password usage and strength
- Commenter believes certification criterion introduction language to be incorrect
- Request to add test step to verify that unique identifier is unique
- Recommendation to consolidate test steps that are repeated in each test section



Auditable events and tamper-resistance.

- i. Record actions. EHR technology must be able to:
 - A. Record actions related to electronic health information in accordance with the standard specified in § 170.210(e)(1);
 - B. Record the audit log status (enabled or disabled) in accordance with the standard specified in § 170.210(e)(2) unless it cannot be disabled by any user; and
 - C. Record the encryption status (enabled or disabled) of electronic health information locally stored on end-user devices by EHR technology in accordance with the standard specified in § 170.210(e)(3) unless the EHR technology prevents electronic health information from being locally stored on end-user devices (see 170.314(d)(7) of this section).
- ii. Default setting. EHR technology must be set by default to perform the capabilities specified in paragraph (d)(2)(i)(A) of this section and, where applicable, paragraphs (d)(2)(i)(B) or (d)(2)(i)(C), or both paragraphs (d)(2)(i)(B) and (C).
- iii. When disabling the audit log is permitted. For each capability specified in paragraphs (d)(2)(i)(A), (B), and (C) of this section that EHR technology permits to be disabled, the ability to do so must be restricted to a limited set of identified users.
- iv. Audit log protection. Actions and statuses recorded in accordance with paragraph (d)(2)(i) must not be capable of being changed, overwritten, or deleted by the EHR technology.

Record Default Setting—evaluates that the EHR technology has the capability to be set by default to record actions related to electronic health information and, where applicable, to record either audit log status or encryption status, or to record both audit log status and encryption status

Permit Audit Log Disabling—evaluates the capability of the EHR technology, as applicable, to restrict disabling of audit logs, disabling of audit log status, and disabling of encryption status to a limited set of identified users

Record Actions—evaluates the capability of the EHR technology audit log function to record information related to an action that is made in respect to electronic health information while the EHR technology is in use

Protect Audit Log—evaluates the capability of the EHR technology to prevent audit logs from being changed, overwritten or deleted by the EHR technology, including recording of actions related to electronic health information, recording of audit log status, and recording of encryption status

Detect Audit Log Alteration—evaluates the capability of the EHR technology to detect whether the audit log has been altered

Test Procedure Comments

- Request for clarification on the difference between disabling audit log vs. audit log status
- Clarify how to demonstrate test step if EHR is incapable of performing function described
- Test steps involving hashing are too limiting
- Suggestion to add a test step instructing Tester to re-enable audit/encryption status after disabling
- Request to consolidate test steps that are repeated in each test section
- Request for test steps to address attacks from outside sources
- Request for clarification on actions listed in standard
- Suggest that Network Time Protocol Test should be altered and/or an alternative attestation option should be provided
- Request for clarification on what qualifies as “disabling”
- Incorrect certification criterion language

Cert.
CriterionAudit reports.

Enable a user to create an audit report for a specific time period and to sort entries in the audit log according to each of the data specified in the standards at § 170.210(e).

TP
Components

Create Audit Report – evaluates the capability of the EHR technology to enable a user to generate an audit report for a specific time period

Sort Audit Log Entries – evaluates the capability of the EHR technology to enable a user to sort entries in the audit log or in an audit report

Public Review Summary

Test Procedure Comments

- Request for clarification on required actions
- Concern that Tester has no obligation to confirm validity of events in audit log
- Request to eliminate requiring provision of audit log with 10 entries
- Incorrect name within certification criterion language
- Request for clarification on whether date and time fields must be combined or separate



End-user device encryption.

Paragraph (d)(7)(i) or (ii) of this section must be met to satisfy this certification criterion.

- i. EHR technology that is designed to locally store electronic health information on end-user devices must encrypt the electronic health information stored on such devices after use of EHR technology on those devices stops.
 - A. Electronic health information that is stored must be encrypted in accordance with the standard specified in § 170.210(a)(1).
 - B. Default setting. EHR technology must be set by default to perform this capability and, unless this configuration cannot be disabled by any user, the ability to change the configuration must be restricted to a limited set of identified users.
- ii. EHR technology is designed to prevent electronic health information from being locally stored on end-user devices after use of EHR technology on those devices stops.

Encrypt – evaluates the capability to encrypt by default electronic health information stored locally on end-user devices after normal use of the EHR technology on those devices stops

Prevent – evaluates the capability to prevent electronic health information from being locally stored on end-user devices after normal use of the EHR technology on those devices stops

Test Procedure Comments

- Some EHRs have no control over how end-user devices store data
- EHRs are not currently required to demonstrate cache-control capabilities
- Vendors are currently not required to provide a list of recommended browsers
- Request for clarification on what data needs to be encrypted
- Request to add test step regarding code review and/or algorithm testing



Cert. Criterion

Transmission to public health agencies

Syndromic surveillance. EHR technology must be able to electronically create syndrome-based public health surveillance information for electronic transmission in accordance with:

i. Ambulatory setting only.

A. The standard specified in § 170.205(d)(2).

B. Optional. The standard (and applicable implementation specifications) specified in § 170.205(d)(3).

ii. Inpatient setting only. The standard (and applicable implementation specifications) specified in § 170.205(d)(3).

TP Components

Create – evaluates the capability of the EHR technology to electronically generate conformant HL7 messages for syndromic surveillance information

Public Review Summary

Test Procedure Comments

- Clarification on how it will be verified that the measures are “ongoing” as compared to Stage 1’s single test instance requirement
- Request to specify the generation of ADT messages

Test Data Comments

- Request clarification on whether Urgent Care cases could be relevant for ambulatory setting



Cert. Criterion

Data portability.

Enable a user to electronically create a set of export summaries for all patients in EHR technology formatted according to the standard adopted at § 170.205(a)(3) that represents the most current clinical information about each patient and includes, at a minimum, the Common MU Data Set and the following data expressed, where applicable, according to the specified standard(s):

A. Encounter diagnoses. The standard specified in § 170.207(i) or, at a minimum, the version of the standard at § 170.207(a)(3);

B. Immunizations. The standard specified in § 170.207(e)(2); (C) Cognitive status; (D) Functional status; and (E) Ambulatory setting only. The reason for referral; and referring or transitioning provider's name and office contact information. (F) Inpatient setting only. Discharge instructions.

TP Components

Create – evaluates the capability for the EHR technology to enable a user to create a set of export summaries for all patients in EHR technology according to the Implementation Guide for CDA® Release 2.0, Consolidated CDA Templates; and including, at a minimum: Encounter diagnoses in the named standard; Immunizations in the named standard; Cognitive status; Functional status; In ambulatory settings only, reason for referral and referring or transitioning provider's name and office contact information; In inpatient settings only, discharge instructions; and The Common MU Data Set data with named standards as appropriate:

Public Review Summary

Test Procedure Comments

- Suggest adding test step for vendors to identify total number of patients to verify accuracy of full set of C-CDAs exported
- Request additional instruction that the Tester will select the specific value within the range of ONC-supplied test data
- Request explicit instruction that a minimum of three and maximum of five test C-CDAs should be validated for test data selected by Tester and entered during the test
- During Global QA, ensure C-CDA conformance testing appears consistently in Inspection Test Guide
- Request explicit instruction that there is no requirement for a vocabulary standard for Cognitive and Functional status
- Clarify that “Set of export summaries” refers to a single document in C-CDA format for all patients in the EHR
- User of metric versus imperial units of measurement; redundant test steps; errors
- Request explicit reference and instruction for machine and human readability of data elements with vocabulary standards

Test Data Comments

- Suggest removing allergy severity levels, family members as Care Team members
- Clarify vocabulary requirements for Procedures
- Specify recording requirements for BP
- Clarify ICD-9 CM requirements



Cert. Criterion

Amendments.

Enable a user to electronically select the record affected by a patient's request for amendment and perform the capabilities specified in paragraphs (d)(4)(i) or (ii) of this section.

- i. Accepted amendment. For an accepted amendment, append the amendment to the affected record or include a link that indicates the amendment's location.
- ii. Denied amendment. For a denied amendment, at a minimum, append the request and denial of the request to the affected record or include a link that indicates this information's location.

TP Components

Record – evaluates the capability for a user to electronically record the patient's request for amendment

Acceptance – evaluates the capability to electronically append acceptance of an amendment to the affected record or include a link that indicates the location of an accepted amendment

Denial – evaluates the capability to electronically append an amendment request and denial of the request to the affected patient record or include a link that indicates the location of a denied amendment

Public Review Summary

Test Procedure Comments

- Clarify acceptability of amendment storage in a separate “log” in the EHR vs. storage in “main” patient record only
- Added requirement in: DTR170.314.d.4 – 1 “record a patient's request for an amendment”
- New requirement: TE170.314.d.4-2.04 and TE170.314.d.4-3.04 require the tester to record the source of the amended information separately from the amendment
- Location of date and time associated with amendment should be in audit log per final rule



Cert. Criterion

Ambulatory setting only—secure messaging.

Enable a user to electronically send messages to, and receive messages from, a patient in a manner that ensures:

- i. Both the patient (or authorized representative) and EHR technology user are authenticated; and
- ii. The message content is encrypted and integrity-protected in accordance with the standard for encryption and hashing algorithms specified at § 170.210(f).

TP Components

Send – evaluates the capability for using the EHR technology to send messages to a patient and an authorized patient representative based on authentication of users/patients/patient representatives and use of encryption in accordance with any encryption and hashing algorithm identified by the National Institute of Standards and Technology (NIST) as an approved security function in Annex A of the Federal Information Processing Standards (FIPS) Publication 140-2

Receive – evaluates the capability for using the EHR technology to receive messages from a patient and an authorized patient representative based on authentication of users/patients/patient representatives and use of encryption in accordance with any encryption and hashing algorithm identified by the National Institute of Standards and Technology (NIST) as an approved security function in Annex A of the Federal Information Processing Standards (FIPS) Publication 140-2

Public Review Summary

Test Procedure Comments

- Requirements for authorized patient representative methods to send/receive patient messages
- Use of 3rd party software for patients to support data exchange vs. direct EHR login
- Verify encryption and integrity criteria capabilities of secure messages sent/ received
- Sharing of authentication or encryption information “out-of-band” with the patient to enable access to information vs. electronic and automatic sharing



Cert. Criterion

Safety-enhanced design.

User-centered design processes must be applied to each capability an EHR technology includes that is specified in the following certification criteria: § 170.314(a)(1); § 170.314(a)(2); § 170.314(a)(6); § 170.314(a)(7); § 170.314(a)(8); § 170.314(a)(16); § 170.314(b)(3); and § 170.314(b)(4).

TP Components

Submit User-Centered Design Practice – evaluates Vendor-supplied documentation of referenced UCD practice to ensure the Vendor has applied user-centered design (UCD) process(es) for each EHR technology capability submitted for testing and specified in the following certification criteria: § 170.314(a)(1) Computerized provider order entry, § 170.314(a)(2) Drug-drug, drug-allergy interaction checks, § 170.314(a)(6) Medication list, § 170.314(a)(7) Medication allergy list, § 170.314(a)(8) Clinical decision support, § 170.314(a)(16) Inpatient setting only - electronic medication administration record, § 170.314(b)(3) Electronic prescribing, § 170.314(b)(4) Clinical information reconciliation

Submit Summative Testing Results for Select Certification Criteria – evaluates Vendor-provided NISTIR 7742 (Customized Common Industry Format Template for Electronic Health Record Usability Testing) for usability test report(s) to ensure the Vendor has conducted summative usability testing and recorded the results for each EHR technology capability submitted for testing and specified in the following certification criteria: § 170.314(a)(1) Computerized provider order entry, § 170.314(a)(2) Drug-drug, drug-allergy interaction checks, § 170.314(a)(6) Medication list, § 170.314(a)(7) Medication allergy list, § 170.314(a)(8) Clinical decision support, § 170.314(a)(16) Inpatient setting only - electronic medication administration record, § 170.314(b)(3) Electronic prescribing, § 170.314(b)(4) Clinical information reconciliation

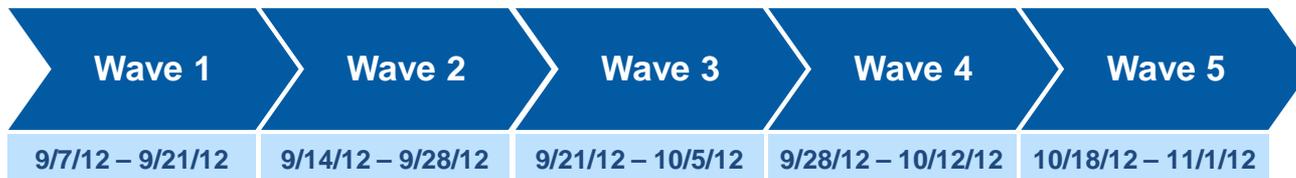
Public Review Summary

Test Procedure Comments

- Clarify whether personalized implementation of NISTIR 7742 CIF template is acceptable vs. NISTIR 7742 template
- Test procedure verifies usability rules applied but does not validate results
- Summative testing when each functionality has been developed, not when new versions if functionality is unchanged
- Consider separate reporting of all criteria, or ability to report some criteria as sub-chapters
- Clarify difference between: TP provides test case scenarios for criteria and: CDS uses scenario from criterion testing.
- User tasks prioritized by risk are redundant because ONC already prioritized criteria by risk
- Expectations for legacy systems to re-do UCD



Draft Test Method Review – Wave 5



Wave 5 (4 Test Procedures)

Revised	170.314(b)(2)	Transitions of care—Create and transmit transition of care/referral summaries
	170.314(f)(4)	Inpt. setting only—Transmission of reportable lab tests and values/results
New	170.314(b)(3)	Electronic prescribing*
	170.314(e)(1)	View, download, and transmit to 3rd party

*eRx is new for inpatient and revised for ambulatory setting.



Cert. Criterion

Transitions of care - create and transmit summary care records

- i. Create. Enable a user to electronically create a transition of care/referral summary formatted according to the standard adopted at § 170.205(a)(3) that includes, at a minimum, the Common MU Data Set and the following data expressed, where applicable, according to the specified standard(s):
 - (A) Encounter diagnoses. The standard specified in § 170.207(i) or, at a minimum, the version of the standard specified § 170.207(a)(3);
 - (B) Immunizations. The standard specified in § 170.207(e)(2);
 - (C) Cognitive status;
 - (D) Functional status; and
 - (E) Ambulatory setting only. The reason for referral; and referring or transitioning provider's name and office contact information.
 - (F) Inpatient setting only. Discharge instructions.
- ii. Transmit. Enable a user to electronically transmit the transition of care/referral summary created in paragraph (b)(2)(i) of this section in accordance with:
 - (A) The standard specified in § 170.202(a).
 - (B) Optional. The standards specified in § 170.202(a) and (b).
 - (C) Optional. The standards specified in § 170.202(b) and (c).

TP Components

Create – evaluates the capability to create a transition of care/referral summary from the EHR in C-CDA format. Included in the test procedure is an evaluation of the capability to use specified vocabularies as defined by the referenced standards.

Transmit - Evaluates the capability of EHR technology to allow a provider to electronically transmit the health information created in the “Create” section of the test procedure another provider or next setting of care:

Public Review Summary

TBD



Cert. Criterion

Inpatient setting only—transmission of reportable laboratory tests and values/results. EHR technology must be able to electronically create reportable laboratory tests and values/results for electronic transmission in accordance with:

- The standard (and applicable implementation specifications) specified in § 170.205(g); and
- At a minimum, the versions of the standards specified in § 170.207(a)(3) and (c)(2).

TP
Components

Create – evaluates the capability of the EHR technology to electronically generate conformant HL7 messages for reportable laboratory test values/results

Public Review
Summary

TBD



Cert. Criterion

Electronic prescribing. Enable a user to electronically create prescriptions and prescription-related information for electronic transmission in accordance with:

- i. The standard specified in § 170.205(b)(2); and
- ii. At a minimum, the version of the standard specified in § 170.207(d)(2).

TP
Components

Create – evaluates the capability of the EHR technology to electronically generate conformant NCPDP and RxNorm prescriptions and prescription related information for electronic transmission.

Public Review
Summary

TBD



View, download, and transmit to 3rd party.

- i. EHR technology must provide patients (and their authorized representatives) with an online means to view, download, and transmit to a 3rd party the data specified below. Access to these capabilities must be through a secure channel that ensures all content is encrypted and integrity-protected in accordance with the standard for encryption and hashing algorithms specified at § 170.210(f). (A) View. Electronically view in accordance with the standard adopted at § 170.204(a), at a minimum, the following data... (B) Download... (C) Transmit to third party...
- ii. Activity history log. (A) When electronic health information is viewed, downloaded, or transmitted to a third-party using the capabilities included in paragraphs (e)(1)(i)(A) through (C) of this section, the following information must be recorded and made accessible to the patient... (B) EHR technology presented for certification may demonstrate compliance with paragraph (e)(1)(ii)(A) of this section if it is also certified to the certification criterion adopted at § 170.314(d)(2)

View Health Information – Evaluates the capability for the EHR to provide patients and authorized representatives a secure, electronic view of the following information: For both ambulatory and inpatient settings: the Common MU Data Set data with named standards as appropriate (in their English representation if they associate with a vocabulary/code set):

Download Health Information – Evaluates the capability to electronically download the information that was viewed as part of the “View” step in a human readable format or a format in accordance with the Implementation Guide for CDA® Release 2.0, Consolidated CDA Templates.

Transmit – Evaluates the capability of EHR technology to allow a patient and a patient’s authorized representative to electronically transmit the health information available for download in the “Download” section of the test procedure to a third party as an ambulatory or inpatient summary (as applicable to the setting for which the EHR technology will be tested); and for inpatient settings only, a transition of care/referral summary:

Record and Display Actions – Evaluate the capability of the EHR technology to capture date, time, and user who views, downloads and transmits health information and make it accessible to the patient (or their authorized representative).

Submit and Verify Summative Testing Results for WCAG Conformance – Evaluates Vendor-supplied documentation of referenced practice, testing tools, tool results, and accompanying documentation to ensure the Vendor has achieved conformance with Web Content Accessibility Guidelines (WCAG) 2.0 Level “A” for each EHR technology capability submitted for testing for viewing of health information by a patient or their authorized representative.

TBD



Draft Test Method Review – Wave 6



Wave 6 (5 Test Procedures*)

Revised	170.314(c)(1)	Clinical quality measures—capture and export
	170.314(c)(2)	Clinical quality measures—import and calculate
	170.314(c)(3)	Clinical quality measures—electronic submission
	170.314(g)(2)	Automated measure calculation
New	170.314(g)(1)	Automated numerator recording

*Drafts are combined into 2 test procedures:

- Clinical quality measures; and
- Automated numerator recording and automated measure calculation



Clinical quality measures.

1. Clinical Quality Measures – capture and export.
 - i. Capture. For each and every CQM for which the EHR technology is presented for certification, EHR technology must be able to electronically record all of the data identified in the standard specified at § 170.204(c) that would be necessary to calculate each CQM. Data required for CQM exclusions or exceptions must be codified entries, which may include specific terms as defined by each CQM, or may include codified expressions of “patient reason,” “system reason,” or “medical reason.”
 - ii. Export. EHR technology must be able to electronically export a data file formatted in accordance with the standards specified at § 170.205(h) that includes all of the data captured for each and every CQM to which EHR technology was certified under paragraph (c)(1)(i) of this section. (2) Clinical Quality Measures – import and calculate.
2. Clinical Quality Measures – import and calculate
 - i. Import. EHR technology must be able to electronically import a data file formatted in accordance with the standard specified at § 170.205(h) and use such data to perform the capability specified in paragraph (c)(2)(ii) of this section. EHR technology presented for certification to all three of the certification criteria adopted in paragraphs (c)(1) through (3) of this section is not required to meet paragraph (c)(2)(i)
 - ii. Calculate. EHR technology must be able to electronically calculate each and every clinical quality measure for which it is presented for certification.
3. Clinical Quality Measures – electronic submission. Enable a user to electronically create a data file for transmission of clinical quality measurement data:
 - i. In accordance with the standards specified at § 170.205(h) and (k); and
 - ii. That can be electronically accepted by CMS.

Prepare – Create the test data set for the EHR SUT – create the test patient data using Cypress for the CQMs on which the EHR system is expected to report.

Execute – Electronically generate clinical quality measure artifacts – evaluates the capability of the EHR SUT to electronically generate the proper CQM artifacts for the CQMs being certified.

Submit – Electronically submit and verify generated CQM artifacts – evaluates the capability of EHRs to electronically submit a) calculated quality measures in accordance with the standard and implementation specifications; and b) exported patient data sufficient to allow external calculation.

Verify – Verify electronic and accurate generation of clinical quality measure artifacts – evaluates the capability to electronically and accurately generate CQM artifacts appropriate for each phase of the test procedure.

TBD



Cert. Criterion

Automated numerator recording. For each meaningful use objective with a percentage-based measure, EHR technology must be able to create a report or file that enables a user to review the patients or actions that would make the patient or action eligible to be included in the measure's numerator. The information in the report or file created must be of sufficient detail such that it enables a user to match those patients or actions to meet the measure's denominator limitations when necessary to generate an accurate percentage.

Automated measure calculation. For each meaningful use objective with a percentage-based measure that is supported by a capability included in an EHR technology, electronically record the numerator and denominator and create a report including the numerator, denominator, and resulting percentage associated with each applicable meaningful use measure.

TP
Components

Record – evaluates the capability to electronically record the numerator and denominator for each meaningful use objective with a percentage-based measure

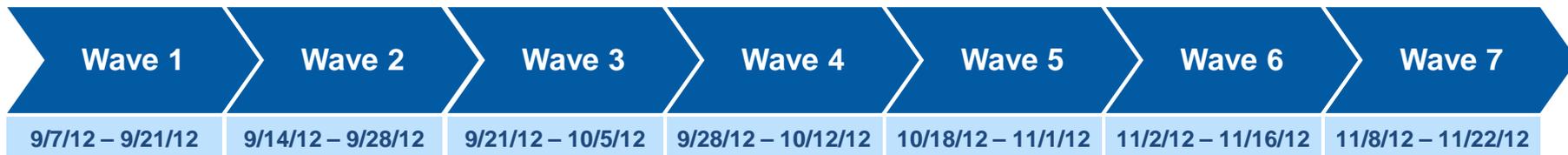
Report – evaluates the capability to create a report that includes the numerator, denominator, and resulting percentage for §170.314 g.2 and numerator only for §170.314 g.1 associated with each percentage-based meaningful use measure

Public Review
Summary

TBD



Draft Test Method Review – Wave 7



Wave 7 (4 Test Procedures)

Revised

- 170.314(b)(1) Transitions of care—Receive, display, and incorporate summary care records
- 170.314(b)(5) Incorporate lab tests and values/results

New

- 170.314(b)(6) Inpt. setting only—Transmission of e-lab test and values/results to Amb provider
- 170.314(g)(4) Quality management system



Transitions of care – receive, display, and incorporate transition of care/referral summaries.

- i. Receive – EHR technology must be able to electronically receive transition of care/referral summaries in accordance with:
 - A. The standard specified in §170.202(a).
 - B. *Optional*. The standards specified in §170.202(a) and (b).
 - C. *Optional*. The standards specified in §170.202(b) and (c).
- ii. Display – EHR technology must be able to electronically display in human readable format the data included in transition of care/referral summaries received and formatted according to any of the following standards (and applicable implementation specifications) specified in: §170.205(a)(1), §170.205(a)(2), and §170.205(a)(3).
- iii. Incorporate. Upon receipt of a transition of care/referral summary formatted according to the standard adopted at §170.205(a)(3), EHR technology must be able to:
 - A. Correct patient. Demonstrate that the transition of care/referral summary received is or can be properly matched to the correct patient.
 - B. Data incorporation. Electronically incorporate the following data expressed according to the specified standard(s):
 1. Medications. At a minimum, the version of the standard specified in §170.207(d)(2);
 2. Problems. At a minimum, the version of the standard specified in §170.207(a)(3);
 3. Medication allergies. At a minimum, the version of the standard specified in §170.207(d)(2).
 - C. Section views. Extract and allow for individual display each additional section or sections (and the accompanying document header information) that were included in a transition of care/referral summary received and formatted in accordance with the standard adopted at §170.205(a)(3).

Receive – evaluates the capability of EHR technology to electronically receive a transition of care/referral summary for a test patient from both ambulatory and inpatient care settings

Display – evaluates the capability of the EHR technology to electronically display, in human readable format, the transition of care/referral summary that was received in the “Receive” step

Incorporate data – evaluates that the EHR technology electronically incorporates medication, problem, and medication allergy list data from the transition of care/referral summary received in the “Receive” step

TBD



Cert. Criterion

Incorporate laboratory tests and values/results.

- i. Receive results.
 - A. Ambulatory setting only.
 1. Electronically receive and incorporate clinical laboratory tests and values/results in accordance with the standard specified in §170.205(j) and, at a minimum, the version of the standard specified in §170.207(c)(2).
 2. Electronically display the tests and values/results received in human readable format.
 - B. Inpatient setting only. Electronically receive clinical laboratory tests and values/results in a structured format and electronically display such tests and values/results in human readable format.
- ii. Electronically display all the information for a test report specified at 42 CFR 493.1291(c)(1) through (7).
- iii. Electronically attribute, associate, or link a laboratory test and value/result with a laboratory order or patient record.

TP Components

Receive, incorporate, and display – evaluates the capability of the ambulatory EHR technology to electronically receive and incorporate clinical laboratory tests and values/results and evaluates the capability of the ambulatory EHR technology to electronically display, in human readable format, the clinical laboratory tests and values/results that were received

Display test report information – evaluates the capability of the ambulatory EHR technology to electronically display the following seven components of test report information for the clinical laboratory tests and values/results

Attribute, associate, or link – evaluates the capability of the ambulatory EHR technology to electronically attribute, associate, or link a lab test and value/result with the appropriate lab order or with the appropriate patient record

Public Review Summary

TBD

New

§170.314(b)(6) Inpt. setting only – Transmission of e-lab test and values/results to Amb. provider



Cert. Criterion

Inpatient setting only — transmission of electronic laboratory tests and values/results to ambulatory providers. EHR technology must be able to electronically create laboratory test reports for electronic transmission in accordance with the standard specified in §170.205(j) and with laboratory tests expressed in accordance with, at a minimum, the version of the standard specified in §170.207(c)(2).

TP Components

Create – evaluates the capability of the inpatient EHR technology to electronically generate conformant HL7 messages for clinical laboratory tests and values/results reports

Public Review Summary

TBD



Cert. Criterion

Quality management system. For each capability that an EHR technology includes and for which that capability's certification is sought, the use of a Quality Management System (QMS) in the development, testing, implementation and maintenance of that capability must be identified.

- i. If a single QMS was used for applicable capabilities, it would only need to be identified once.
- ii. If different QMS were applied to specific capabilities, each QMS applied would need to be identified. This would include the application of a QMS to some capabilities and none to others.
- iii. If no QMS was applied to all applicable capabilities such a response is acceptable to satisfy this certification criterion.

TP Components

Identify - Verifies that for each capability that an EHR technology includes and for which that capability's certification is sought, the use of a Quality Management System (QMS) in the development, testing, implementation and maintenance of that capability is identified.

Public Review Summary

TBD



Conclusion

Summary

- Launched ONC HIT Certification Program
- Revamping CHPL for a 3.0 release
- Reviewing 2014 Ed. Test Method

Future Activities

- Final Test Methods posted in mid-December 2012
- 2014 Ed. Testing and Certification begin January 2, 2013
- CHPL 3.0 implemented on January 2, 2013

Resources

- This presentation will be posted on the ONC website
- [About Certification](#)
- [2014 Edition Draft Test Methods](#)