

The Office of the National Coordinator for
Health Information Technology



Leveraging the EHR Certification Program for Clinical Data Extraction

State Innovation Model Program

Health IT Resource Center

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Consultant



Putting the **I** in Health **IT**
www.HealthIT.gov

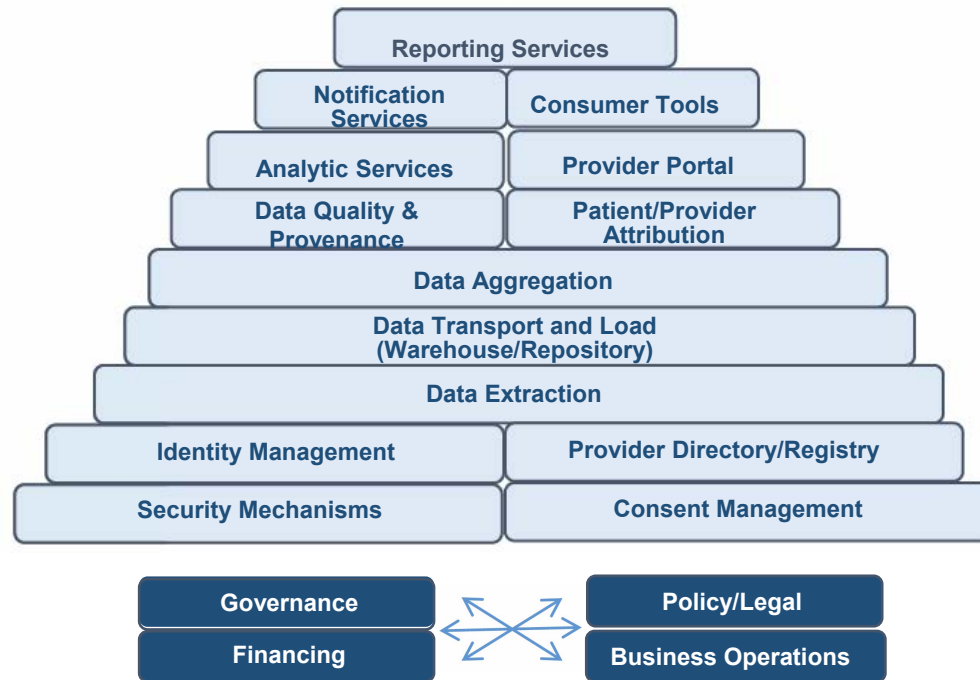


- 25 min
 - Context – **Mark Monterastelli, ONC Consultant SME**
 - How Data Extraction fits into the Resource Center HIT Stack for Value Based Payment
 - Overview of the ONC EHR Certification Program
 - Certification vs. Meaningful Use
 - Certified Functions for Data Extraction
 - Data Available and Formats
 - Certification Validation
 - Information Blocking and Surveillance
- 25 min
 - Real world stories – **Dr. David Kendrick – MyHealth Access & ONC Consultant SME**
- 10 min
 - Questions and Discussion

Conflict of Interest Disclosures

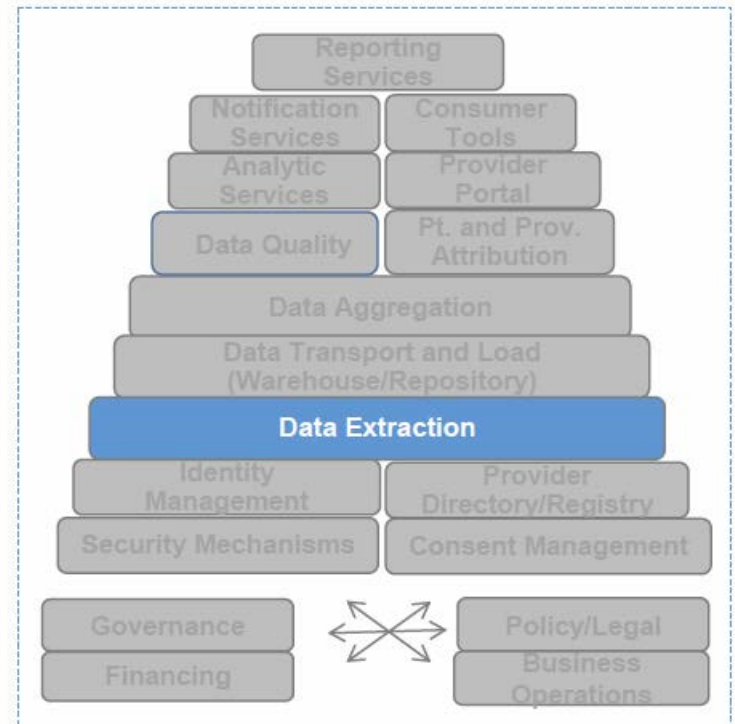
Health IT Infrastructure to create a state wide (or regional) Shared Services to support payment reform models

Shared Services
Gain efficiency through reusable shared technical services



Techniques and tactical options for extracting **clinical data** from electronic health records.

- HL7 messaging integration
 - Primary Source – ~90% of clinical data exchange
- Direct database interface (reverse engineering)
 - Practical for larger IDNs with reasonable IT budgets and relatively few EHR systems
- Certified functions for data exchange and measurement
 - Emerging method, more highly structured and coded, context oriented
 - Potentially less overall cost



- The HITECH Act of 2009 gave ONC the authority for a permanent certification program for health information technology
- Certification provides assurance to purchasers and other users that a system meets the technological capabilities, functionality and security requirements adopted by HHS.
- Vendors have their products tested by an Accredited Testing Lab and once certified the products are posted to the Certified Health IT Product List (CHPL).

Certification vs. Meaningful Use

Certification defines and tests the functions of health information technology deemed by ONC to be important.

Meaningful Use pays incentive dollars to use certified health information technology in specific ways deemed by CMS to be in the best interest of the delivery system.

				MEANINGFUL USE	MEANINGFUL USE	2014 Edition EHR CERTIFICATION CRITERIA
				42 CFR 495.6(j)-(m)	42 CFR 495.6(j)-(m)	45 CFR 170.314
EP	EH	Stage 2 Objective		Stage 2 Measure		
CORE	EP	EH	Record smoking status for patients 13 years old or older.	More than 80% of all unique patients 13 years old or older seen by the EP or admitted to the EH's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period have smoking status recorded as structured data.		§170.314(a)(11)
				*Exclusions apply: see CMS rule for details	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).	

Certified Functions for Data Extraction

- ✓ 170.314(a)(14) PATIENT LIST CREATION
- ✓ 170.314(a)(15) PATIENT-SPECIFIC EDUCATION RESOURCES
- ✓ 170.314(b)(1) TRANSITIONS OF CARE - RECEIVE, DISPLAY, AND INCORPORATE TRANSITION OF CARE/REFERRAL SUMMARIES
- ✓ 170.314(b)(2) TRANSITIONS OF CARE - CREATE AND TRANSMIT TRANSITION OF CARE/REFERRAL SUMMARIES
- ✓ 170.314(b)(3) ELECTRONIC PRESCRIBING
- ✓ 170.314(b)(4) CLINICAL INFORMATION RECONCILIATION
- ✓ 170.314(b)(5) INCORPORATE LABORATORY TESTS AND VALUES/RESULTS
- ✓ 170.314(b)(7) DATA PORTABILITY
- ✓ 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(d)(1) AUTHENTICATION, ACCESS CONTROL, AND AUTHORIZATION
- ✓ 170.314(d)(2) AUDITABLE EVENTS AND TAMPER-RESISTANCE
- ✓ 170.314(d)(3) AUDIT REPORT(S)

Create and Transmit Transition of Care/Referral Summaries

2014 CDA#1
Test Procedure for §170.314(b)(2) Transitions of care - create and transmit summary care records
Approved Test Procedure Version 1.0 March 1, 2011

Test Procedure for §170.314 (b)(2) Transitions of care – create and transmit summary care records

This document describes the test procedure for evaluating performance of EHR technology to the certification criteria defined in 45 CFR Part 170 Subpart C of the Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition, Revisions to the Permanent Certification Program for Health Information Technology, Final Rule. The document is organized by test procedure and derived test requirements with accessibility to the normative certification criteria as described in the Overview document located at <http://www.healthit.gov/certification> (navigation bar updated to reflect on-going feedback received).

The Department of Health and Human Services (HHS) Information Technology (ONC) has defined the standard used in this test procedure. Applicability and interpretation criteria to EHR technology is determined by the Permanent Certification Program ("on-notice" later Certification Program) is carried out by National Voluntary Accredited Testing Laboratories (ATLs) as part of the Certification Program (Establishment of the Federal Health Information Technology, 45 CFR Part 170, February 7, 2011).

Questions or concerns regarding the ONC HIT Certification are at www.onccertification.gov.

CERTIFICATION CRITERIA

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

§170.314(b)(2) 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).

§170.314(b)(2) 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):

C-CDA

HL7 Implementation Guide for CDA Release 2: IHE Health Story Consolidation

<https://www.law.cornell.edu/cfr/text/45/170.205>

Test Procedure for §170.314(b)(7) Data portability

This document describes the test procedure for evaluating conformance of EHR technology to the certification criteria defined in 45 CFR Part 170 Subpart C of the Health Information Technology Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition, Revision 1 to the Permanent Certification Program for Health Information Technology, Final Rule. The document is organized by test procedure and derived test requirements with flexibility to the most like certification criteria as described in the Overview document located at <https://www.fda.gov/oc/2014/03/03/170-314-b-7-2014-edition-test-method>. This test procedure may be updated to reflect on-going feedback received during the conformance activities.

The Department of Health and Human Services Information Technology (HHS IT) has developed a set of test procedures. Additionally, a set of certification criteria for EHR technology under the Permanent Certification Program (Permanent Certification Program) is established by HHS IT. Accredited Testing Laboratories (ATLs) under the Certification Program (Establishment of the Certification Program) (45 CFR Part 170, February 17, 2014).
[Questions or comments regarding the HHS IT Certification Program](https://www.fda.gov/oc/2014/03/03/170-314-b-7-2014-edition-test-method)

CERTIFICATION CRITERIA

This Certification Criteria is for the Health Information Technology Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition/Revisions to the Permanent Certification Program for Health Information Technology, Final Rule (September 4, 2014).

§170.314(b)(7) 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):

§170.314(b)(7) 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):

C-CDA

HL7 Implementation Guide for CDA Release 2: IHE Health Story Consolidation

<https://www.law.cornell.edu/cfr/text/45/170.205>

Renamed “Common Clinical Dataset”

Patient name	Lab values/results
Sex	Vital signs
Date of birth	Procedures
Race	Care team members
Ethnicity	Immunizations
Preferred language	Unique device identifiers for implantable devices
Problems	Assessment and plan of treatment
Medications	Goals
Medication allergies	Health concerns
Lab tests	

C-CDA and QRDA

- Two formats are specified:
 - C-CDA
 - QRDA Category 1
 - Difference between Cat 1,3

Both are based on the Clinical Document Architecture

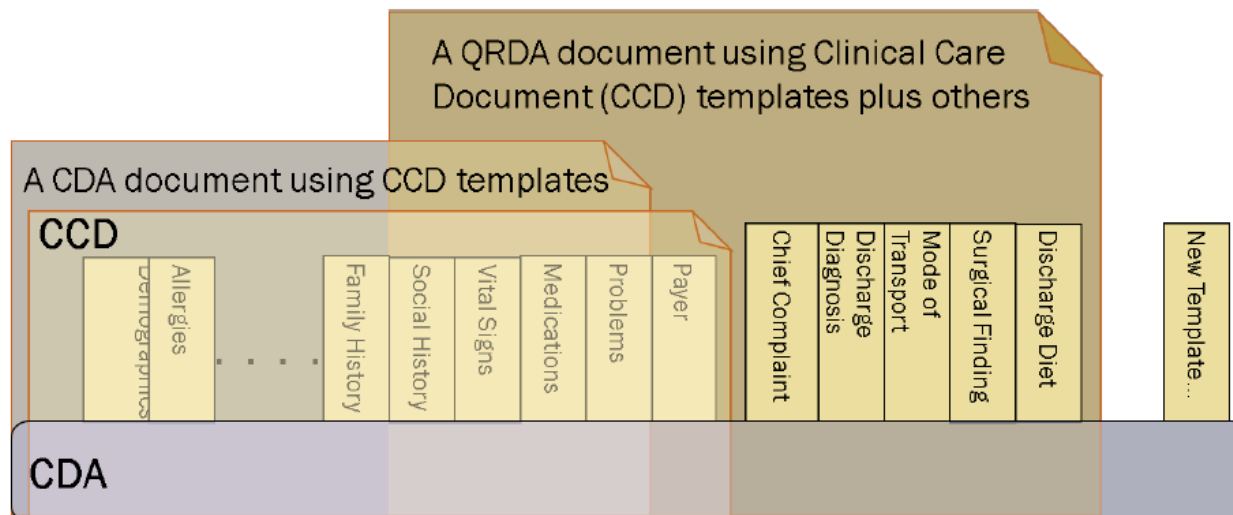
Terminology Warning

“CCD”

- Continuity of Care Document
- Clinical Care Document
- Common Clinical Dataset
- Consolidated Clinical Document

“C-CDA”

- Consolidated Clinical Document Architecture



Validate Certification using CHPL

Certified Health IT Product List

Vendor Name

Q
Search
Clear Search >

YOUR PRODUCTS (2)

✖ PowerChart (All CQMs)

✖ Amazing Charts

View Progress

STATUS

Base Criteria 100% Inpatient CQMs 100%

CQM Domains 100% Ambulatory CQMs 100%

* Additional certification criteria may need to be added in order to meet submission requirements for Medicaid and Medicare programs.

	PRODUCT	VERSION	PRACTICE TYPE	CLASSIFICATION	CERTIFICATION EDITION	VENDOR	CHPL PRODUCT NUMBER
Use Search Filters Below							
CERTIFICATION EDITION							
2014 <input checked="" type="checkbox"/>							
PRACTICE TYPE							
Ambulatory <input type="checkbox"/>							
Inpatient <input type="checkbox"/>							
CLASSIFICATION							
Modular EHR <input type="checkbox"/>							
Complete EHR <input type="checkbox"/>							
CERTIFICATION CRITERIA (58)							
170.314(a)(1) <input type="checkbox"/>							
170.314(a)(2) <input checked="" type="checkbox"/>							
170.314(a)(3) <input type="checkbox"/>							

Report to Congress April 2015 - if the behavior of provider organizations or vendors meets the following three criteria, they are considered to be engaging in information blocking:

- **Interference.** There must be “an act or course of conduct that interferes with the ability of authorized persons or entities to access, exchange, or use electronic health information.”
- **Knowledge.** “The decision to engage in information blocking [must be] made knowingly.”
- **No Reasonable Justification.** Conduct must be “objectively unreasonable in light of public policy.”

Registering Complaints

If you are having difficulty with you vendor providing the function they are certified to perform there is process for issuing a complaint.

Issue Reporting Steps for Providers with Certified EHR Technology

STEP 1

Contact Developer

Work with developer to resolve issue.

If issue remains unresolved AND is related to a certified capability contact **ONC-ACB** at Step 2.

STEP 2

Contact ONC-ACB

ONC-Authorized Certification Body

The ONC-ACB will check to see if the reported issue is applicable to one or more certified capabilities.

The ONC-ACB will work with the provider and developer to get more information. It may also perform surveillance to determine if non-conformities exist.

If non-conformities are found, the ONC-ACB will require the developer to implement a corrective action plan.

STEP 3

Contact ONC

ONC will check to see if product in question is certified. If it is, we will refer the matter to the appropriate ONC-ACB at Step 2.

Resources

HEALTH IT PRODUCT COMPLAINTS:

<http://healthit.gov/healthitcomplaints>

CERTIFIED HEALTH IT PRODUCT LIST:

<http://healthit.gov/chpl>

ONC -AUTHORIZED CERTIFICATION BODY (ACB) (PRODUCT COMPLIANCE):

ehr@infogard.com

ehr@iscalabs.com

ehrcomplaints@drummondgroup.com

If developer is unresponsive, contact **ONC-ACB**

If ONC-ACB is unresponsive, contact **ONC**

ONC.Certification@hhs.gov

- New requirements for “in-the-field” surveillance under the ONC Health IT Certification Program
- ONC-ACBs should ensure that certified Health IT Modules can perform certified capabilities in a production environment (when implemented and used)
 - Reactive surveillance (e.g., complaints)
 - Randomized surveillance
(2% of annually certified health IT at one or more location)
- Enhanced surveillance of mandatory transparency requirements
- Non-conformity and corrective action reported to the CHPL beginning in CY 2016



Improve the Reliability
and Transparency of
Certified Health IT

Improve Patient Safety

Real Life Data Extraction Stories

Putting the I in HealthIT
www.HealthIT.gov

David C. Kendrick, MD, MPH

Chair, Department of Medical Informatics, University of Oklahoma

CEO, MyHealth Access Network

Tulsa , OK



<http://www.help.senate.gov/hearings/achieving-the-promise-of-health-information-technology-information-blocking-and-potential-solutions>

- The ONC EHR Certification ensures that functionality exists that can be used to extract data
- The ONC Surveillance program can be used for conformance and enforcement of certified functions
- Data extracted need additional work to be useful in your notification or analytics system

- Listening Event
 - Tomorrow January 27th at 4:00pm EST
 - Dial in: 1-877-501-8576 (P: 3385-3955)
- Potential Affinity Group on Data Extraction
- Additional questions or needs contact your project officer for a TA request

- Mark Monterastelli
 - markmonterastelli@gmail.com
- David Kendrick
 - David-Kendrick@ouhsc.edu