

## **Certified Health IT Product List (CHPL)**

**PUBLIC USER GUIDE** 



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#### Introduction

The ONC Certified Health IT Product List (CHPL) is the authoritative, comprehensive listing of health IT products that have been tested and certified under the Health IT Certification Program administered by the Office of the National Coordinator for Health IT (ONC). ONC compiles information submitted from ONC-Authorized Certification Bodies (ONC-ACBs) to generate a public, centralized, and comprehensive list of certified health IT products: the CHPL. The CHPL also allows health care providers and hospitals to generate Centers for Medicare & Medicaid Services (CMS) Electronic Health Record (EHR) Certification IDs for use in CMS programs, such as the Quality Payment Program and Promoting Interoperability (PI) Programs. The CHPL is designed to provide a streamlined user interface experience and to provide structured data in an open format for the reporting of granular data. In addition, this data is more accessible through the use of application programming interfaces (APIs).

#### How to Search for Certified Products

#### Searching by Certified Product, Developer Name, or ID

- 1. Navigate to the CHPL website: <a href="https://chpl.healthit.gov">https://chpl.healthit.gov</a>
- 2. Enter the name of the developer, product, ONC-ACB ID, or CHPL ID into the search bar, or you can click the "Browse all" button to search without any specific search terms.
  - a. CHPL IDs are unique to each certified product listing. There are two types of CHPL IDs depending on the certified product listing.
    - i. Products certified before March 28, 2016, have CHPL IDs in the following format:
      - 1. CHP-XXXXXX
      - 2. Ex: CHP-022987 will return "axiUm CE"
  - b. Products certified for the first time after March 28, 2016, have CHPL IDs in the following format:
    - i. Edition.ATL.ACB.Developer.Product.Version.ICS.AdditionalSoftware.Date
      - 1. Edition = certification edition (i.e. 2014, 2015)
      - 2. ATL = two digit code for the ONC-Authorized Testing Laboratory (ATL)
      - 3. ACB = two digit code for the ONC-ACB
      - 4. Developer = four digit code for the health IT product developer
      - 5. Product = four character alphanumeric reference to the certified product
      - 6. Version = two character alphanumeric reference to the version of the certified product
      - 7. ICS = two digit code indicating Inherited Certified Status (increments for each listing that certifies through ICS for that product)
      - 8. Relied Upon Software = binary code indicating the requirement for additional software to meeting certification requirements (1= yes, 0 = no)
      - Date = Date of certification (format = YYMMDD)
    - ii. Example: 15.04.04.2891.Sunr.AM.02.1.170929 will return "Sunrise Ambulatory Care"
  - c. ONC-ACB IDs may be different from CHPL IDs. They are generated by each ONC-ACB and may not have a consistent structure. In addition, a single ONC-ACB ID may refer to more than one certified product listing.

*Note*: By default, the CHPL search excludes products without active certificates. To include these products in your search, you should use the filters as described below.

#### Refining Search (Filter)

- 1. The CHPL provides several options for filtering through certified or formerly certified health IT products. The following filter categories are available:
  - a. Certification Status
    - i. Active
    - ii. Retired (off by default)
    - iii. Suspended by ONC
    - iv. Suspended by ONC-ACB
    - v. Terminated by ONC (off by default)
    - vi. Withdrawn by Developer Under Surveillance/Review (off by default)
    - vii. Withdrawn by ONC-ACB (off by default)
  - b. Certification Edition
    - i. 2011 (off by default as this Edition was retired by ONC as of March 1, 2015)
    - ii. 2014
    - iii. 2015
  - c. Certification Criteria
    - i. View 2011 Certification Criteria
    - ii. View 2014 Certification Criteria
    - iii. View 2015 Certification Criteria
  - d. Surveillance Activity
    - i. Has never had a surveillance activity
    - ii. Has had a surveillance activity
    - iii. Never had a Nonconformity
      - 1. Open Nonconformity
      - 2. Closed Nonconformity
  - e. More
    - i. View Clinical Quality Measures
    - ii. View ONC-ACBs (Retired ONC-ACBs are turned off by default 4 months after the ONC-ACB retires)
    - iii. View Practice Type (2014 Edition Products Only)
    - iv. View Certification Date
    - v. Developer
    - vi. Product
    - vii. Version
- 2. Once a filter option has been selected, the CHPL will automatically adjust the search results.
- 3. Remove filters by clicking:
  - a. One of the links that displays under the filters and above the search results:
    - i. The "Browse all" link
    - ii. The "Clear Filters" link
  - b. One of the specific filters by clicking on the clear filter link under the corresponding filter category

#### Downloading Search Results

- 1. Once the search results display what the user wants to view, the user has the ability to download those search results (50 listings maximum each time) using the Download Results dropdown next to the "More" dropdown filter.
- 2. Under the Download Results dropdown (down arrow to a rectangle icon), the following data categories can be included in the export for each listing:
  - a. Edition
  - b. Product data
  - c. Certification Date
  - d. CHPL ID
  - e. ONC-ACB
  - f. Practice Type
  - g. Status
  - h. Details
  - i. Certification Criteria
  - j. Clinical Quality Measures
  - k. Surveillance
- 3. Click the blue download button ("Download ## results").
  - a. If the button does not display under the data categories that can be included in the export, there are more than 50 listings in the search results displayed on the page. The user should either narrow the search results further or change the number of results per page to 50 (located at the bottom of the search result list).
  - b. If the search results include more than 50 listings, the user can walk through the steps on each page to export each one when the number of results per page is set to 50.



#### How to Compare Certified Products

- Navigate to the CHPL website: <a href="https://chpl.healthit.gov">https://chpl.healthit.gov</a>
- 2. Search for the product listings to be compared.
- 3. To compare products, click the green "+Compare" button to the right of each product listing to be compared.
  - a. As each "+Compare" button is selected, the corresponding product listing will be added to the "Compare Products" widget that will automatically appear in the top menu bar in the upper right-hand corner.
  - b. Product listings can be removed by either clicking their name in the 'Compare Products' widget or by clicking the "+Compare" button next to the product listing again to deselect it.

*Note*: While this feature has no technical limit to the number of listings to be compared, comparing five or less at a time is recommended for ease of reading and comparing.

- 4. To maximize or minimize the 'Compare Products' widget, click on the "Compare Products" menu on the top menu bar in the top right-hand corner. When the 'Compare Products' widget minimizes, it does not remove product listings that have already been selected to be compared.
- 5. Once all product listings to be compared are selected, click the blue "Compare products" button at the bottom of the list of product listings to compare in the 'Compare Products' widget.
- 6. Once on the Compare Products screen, to view the comparison of product listings by Certification Criteria, click the blue text "Certification Criteria" link in the left hand side navigation to expand the Certification Criteria list. Click the "Certification Criteria" link again to collapse the section again.
- 7. Once on the Compare Products screen, to view the comparison of product listings by Clinical Quality Measures, click the blue text "Clinical Quality Measures" link in the left hand side navigation to expand the Clinical Quality Measures list. Click the "Clinical Quality Measures" link again to collapse the section again.
- 8. To view additional details about a specific product, click the blue "details" link at the bottom of the product's listing.
- 9. To return to the search results, either click the "Return to search results" link at the top of the Compare Products screen or your browser's back button.



or "False."

### Understanding the Fields Under Certification Criteria<sup>1</sup>

Accessibility Standard – Applies to 2015 Edition certification only. This refers to design that expands access to health IT for people who experience disabilities. When a single accessibility-centered design standard is used, the standard only needs to be identified once. Otherwise, the accessibility-centered design standards need to be identified for every capability to which they were applied, or the developer must state that no accessibility-centered design was used. A non- exhaustive list of such standards can be found here: https://www.healthit.gov/testmethod/accessibility-centered-design#ccg. An allowable value for this attribute would be, for example, "WCAG 2.0 Level AA," or if the product does not meet any accessibility-centered design standard/law, the value should be "none."

Functionality Tested – Applies to 2015 Edition certification only. Includes any optional, alternative, ambulatory, or inpatient capabilities within a certification criterion to which the product was tested and certified. The corresponding paragraph number should be used for the functionality within the regulation. Allowable values for this attribute would be, for example, "Ambulatory: § 170.315(a)(6)(i) Over multiple encounters in accordance with, at a minimum, the version of the standard specified in § 170.207(a)(4)"; or "Alternative: § 170.315(a)(10)(i) Drug formulary checks."

GAP – Gap certification allows ONC-Authorized Certification Bodies (ONC-ACBs) to reuse prior test results for a new certification request on a product that was certified to a previous Edition's certification criterion, so long as the criterion did not change between Editions. For example, a product may be eligible for gap certification for a criterion in the 2015 Edition if previously certified to the 2014 Edition, as long as that criterion did not change. GAP should not be confused with inherited certification, which allows recertification for a newer version of a previously certified product within the same Edition, if that product did not change significantly. More information can be found here: https://www.healthit.gov/sites/default/files/policy/public\_applicability\_of\_gap\_certification\_an d inherited certified status.pdf. Allowable values for the Gap Certification attribute are "True"

Measures Successfully Tested for G1 – This refers to the Automated Numerator Recording certification criterion. For 2015 Edition certification, measures can be found in the "Certification Companion Guide" link to the right of §170.315 (g)(1) located at https://www.healthit.gov/policyresearchers-implementers/2015-edition-test-method. An allowable value for this attribute for 2015 Edition certification would be, for example, "Patient Electronic Access: Eligible Professional."

Measures Successfully Tested for G2 - This refers to the Automated Measure Recording certification criterion. For 2015 Edition certification, measures can be found in the "Test Procedure" link to the right of §170.315 (g)(2) located on the 2015 Edition Test Method home page at https://www.healthit.gov/topic/certification-ehrs/2015-edition-test-method. An allowable

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<sup>&</sup>lt;sup>1</sup>2014 Edition products certified before April 1, 2016, may not have this data available in structured formats on the CHPL because they were certified before this version of the CHPL went live. February 15, 2019



- value for this attribute for 2015 Edition certification would be, for example, "Computerized Provider Order Entry Medications: Eligible Professional."
- Measure Successfully Tested for G1 This refers to the Automated Numerator Recording certification criterion. For 2014 Edition certification, measures can be found in the "Test Procedure" link to the right of §170.314 (g)(1) at <a href="https://www.healthit.gov/policy-researchers-implementers/2014-edition-final-test-method">https://www.healthit.gov/policy-researchers-implementers/2014-edition-final-test-method</a>. An allowable value for this attribute for 2014 Edition certification would be, for example, "False."
- Measure Successfully Tested for G2 This refers to the Automated Measure Recording certification criterion. For 2014 Edition certification, measures can be found in the "Test Procedure" link to the right of §170.314 (g)(2) located on the 2014 Edition Test Method home page at <a href="https://www.healthit.gov/topic/certification-ehrs/2014-edition-test-method">https://www.healthit.gov/topic/certification-ehrs/2014-edition-test-method</a>. An allowable value for this attribute for 2014 Edition certification would be, for example, "True."
- Standard This refers to the standard used to meet a certification criterion where additional, optional standards are permitted. For the 2014 Edition, a list of standards for certification criteria can be found at <a href="https://www.healthit.gov/topic/certification-ehrs/2014-standards-hub">https://www.healthit.gov/topic/certification-ehrs/2014-standards-hub</a>. For the 2015 Edition, a list of standards can be found at <a href="https://www.healthit.gov/topic/certification/2015-standards-hub">https://www.healthit.gov/topic/certification/2015-standards-hub</a>. An allowable value for this attribute would be, for example, "ICD-10-CM", or in the case of no additional, optional standard, "None."
- Privacy and Security Framework Applies to 2015 Edition certification only. Health IT products presented for certification under the Privacy and Security (P & S) framework must be tested to a mandatory minimum set of identified criteria. P & S criteria includes § 170.315(d)(1) through (d)(11), and developers can use one of two approaches to demonstrate conformance: Approach 1 functional demonstration or Approach 2 documentation of integration. For additional guidance, please reference the P & S Certification Companion Guide (CCG) at <a href="https://www.healthit.gov/sites/default/files/2015Ed\_CCG\_Privacy\_and\_Security.pdf">https://www.healthit.gov/sites/default/files/2015Ed\_CCG\_Privacy\_and\_Security.pdf</a>. Allowable values for this attribute or "Approach 1" or "Approach 2."
- Quality Management System All health IT products must be certified to either the 2014 Edition or 2015 Edition Quality Management System criterion ("QMS"), § 170.314(g)(4) or § 170.315(g)(4). For the 2014 Edition, the developer may use an industry standard system, such as ISO 9001, an internally developed system, or no standard. An allowable value for this attribute would be, for example, "none." For the 2015 Edition, the QMS used is either (1) one that has been established by the Federal Government or a standards developing organization (SDO), including, but not limited to: FDA's quality system regulation in 21 CFR part 820, ISO 9001, ISO 14971, ISO 13485, and IEC 62304; or (2) mapped to one or more of the standards established by the Federal Government or an SDO. The tester must verify that any identified gaps have been documented and explained. The specific QMS that was used for each criteria or capability must be identified. For additional guidance, please reference the QMS Certification Companion Guide (CCG) at https://www.healthit.gov/test-method/quality-management-system#ccg. An allowable value for this attribute would be, for example, "Standard: ISO 9001; Description: N/A, Applicable Criteria: All."

- Relied Upon Software Relied upon software is that which was relied upon for testing and certification. It is typically, though not always, third-party software that was not developed by the health IT developer. Relied upon software may be used to demonstrate compliance with a portion of an adopted certification criterion or an entire criterion.
- SED SED is an acronym for safety-enhanced design, which refers to ONC's certification requirements that make user-centered design focused on functionalities central to patient safety, a key part of the design of health IT. The goal of SED is to increase patient safety by correcting for human errors. User-centered design processes must be applied to each capability the health IT product includes from the following certification criteria For the 2014 Edition: § 170.314(a)(1) and (a)(2), § 170.314(a)(6) through (a)(8); § 170.314(a)(16); and § 170.314(b)(3) and (b)(4). For the 2015 Edition § 170.315(a)(1) through (a)(9) and (a)(14), and § 170.315(b)(2) and (b)(3).
- Test data used Test data provides a given set of input to verify that expected results are produced from defined functions during the test and accompanies the associated Edition Test Tools for related certification criteria. This attribute is only relevant for the Automated Numerator Recording criterion [§ 170.314 (g)(1); § 170.315 (g)(1)] and the Automated Measure Calculation criterion [§170.314 (g)(2); § 170.315 (g)(2)]. For the **2014 Edition** certification, an allowable value for this attribute would be, for example, "Version 2.1." For the **2015 Edition** certification, an allowable value for this attribute would be, for example, "EH/CAH; Version 1.3."
- Test procedure version This refers to the version of the test procedure used for testing of the health IT product. The test procedure offers objective guidance to ONC-Authorized Testing Laboratories (ONC-ATLs) and health IT developers as they conduct testing to provide traceability from the certification criteria requirements to testing activities, and to ensure consistency throughout the certification process. Test procedures for the 2014 Edition criteria can be found at the bottom of ONC's Testing and Test Methods webpage at <a href="https://www.healthit.gov/topic/certification-ehrs/2014-edition-test-method">https://www.healthit.gov/topic/certification-ehrs/2015-edition-test-method</a>. An allowable value for this attribute would be, for example, "1.1."
- Test tool Test tools are designed to be used by health IT developers and implementers during the development of software to ensure the software conforms to certification criteria used in the ONC Health IT Certification Program. Test tools will also be used to evaluate conformance to the referenced standards and criteria requirements during testing. A list of ONC-approved 2014 Edition test tools can be found at <a href="https://www.healthit.gov/topic/certification-ehrs/2014-edition-test-method">https://www.healthit.gov/topic/certification-ehrs/2014-edition-test-method</a>. The 2015 Edition certification test tools can be found at <a href="https://www.healthit.gov/topic/certification-ehrs/2015-edition-test-method">https://www.healthit.gov/topic/certification-ehrs/2015-edition-test-method</a>. An allowable value for this attribute would be, for example, "Edge Testing Tool" for the ONC Transport Testing Tool.



#### Understanding Surveillance Information in the CHPL

#### Surveillance Description

In accordance with 170.523(i)(2), ONC-ACBs must report, at a minimum, the results of their surveillance on a quarterly basis. These results are reported to the CHPL and will include the following fields for each certified product that was surveilled:

Surveillance Description Fields	Description
Date Surveillance Began	The date surveillance was initiated.
Date Surveillance Ended	If applicable, the date surveillance was completed.
Surveillance Type	The type of surveillance conducted (either randomized or reactive).
Certification Criteria and	The ONC Health IT Certification Program requirement that was
Program Requirements	surveilled. For example, this may be a specific certification criteria
Surveilled	(e.g., 170.315(a)(1)), a transparency or disclosure requirement (e.g.,
	170.523(k)(1)), another requirement with a regulatory reference
	(e.g., 170.523(I)), or a brief description of the surveilled
	requirement.
Surveillance Result	Whether or not a non-conformity was found for the conducted
	surveillance.
Surveillance Initiated By	Whether surveillance was initiated by ONC-ACB or through ONC
	direct review.

Surveillance does not necessarily mean that there is a problem with the product. ONC-ACBs are required to follow-up on any complaints or potential issues that they are made aware of. ONC-ACBs may also elect to conduct randomized surveillance.

*Note*: Surveillance activities in progress are only reported when a determination is made. If there is a finding of non-conformity, the CHPL records are updated weekly. Otherwise, surveillance activities that result in a conformant finding will be reported quarterly.

#### Non-Conformity

The CHPL lists any discovered non-conformities for each certified product. When an ONC-ACB determines that a certified product does not comply with certification requirements and/or regulations, the certified product is considered non-conforming. A certified product that has been found to be non-conforming does not necessarily indicate that a certified product is "defective." Even when a non-conformity or deficiency has been identified, a developer's proposed corrective action plan (CAP), its efforts to remedy any problems, and notification to affected customers and users can demonstrate commitment to the quality of technology, the user experience, and patient safety. Many non-conformities or deficiencies are resolved quickly.

Developers submit a CAP in response to requests from an ONC-ACB upon the discovery of a non-conformity. In order to be approved by an ONC-ACB, a CAP must include:

- 1. A description of the identified non-conformities or deficiencies;
- 2. An assessment of how widespread or isolated the identified non-conformities or deficiencies may be across all of the developer's customers and users of the certified Complete EHR or

- certified Health IT Module;
- 3. How the developer will address the identified non-conformities or deficiencies, both at the locations under which surveillance occurred and for all other potentially affected customers and users:
- 4. How the developer will ensure that all affected and potentially affected customers and users are alerted to the identified non-conformities or deficiencies, including a detailed description of how the developer will assess the scope and impact of the problem, including identifying all potentially affected customers; how the developer will promptly ensure that all potentially affected customers are notified of the problem and plan for resolution; how and when the developer will resolve the issues for individual affected customers; and how the developer will ensure that all issues are in fact resolved;
- 5. The timeframe under which corrective action will be completed; and
- 6. An attestation by the developer that it has completed all elements of the approved corrective action plan.

The CHPL provides the following information about any non-conformity that a certified product may have:

Non-Conformity Fields	Description
Date of Determination of	The date that the ONC-ACB determined that a non-conformity was
Non-Conformity	present.
Corrective Action Plan	The date that the ONC-ACB approved the CAP proposed by the
Approval Date	developer.
Date Corrective Action Began	The date that the corrective action was started.
Date Corrective Action Must	The date that the corrective action must be completed in order to
be Completed	avoid termination of the certified product's certification status.
Date Corrective Action Plan	The date that the corrective action was completed.
was Completed	
Non-Conformity Type	For non-conformities related to specific regulatory references (e.g.,
	certified capabilities, transparency or disclosure requirements, or use
	of the Certification Mark), the regulation reference is used (e.g.,
	170.315(a)(2) or 170.523(I). If the non-conformity type is designated as
	'Other Non-Conformity', then the associated non-conformity does not
	have a relevant regulatory reference.
Non-Conformity Status	Whether the non-conformity is open or closed (has been resolved).
Non-Conformity Summary	A brief summary describing why the certified product was found to be
	non-conformant.
Findings	A detailed description of the ONC-ACB's findings related to the non-
	conformity. This provides a full picture of the potential non-
	conformities or other deficiencies the ONC-ACB identified, how they
	were evaluated, and how the ONC-ACB reached its non-conformity
	determination.
Developer Explanation	If available, the developer's explanation of why it agrees or disagrees
	with the ONC-ACB's assessment of the non-conformity and an
	explanation of why the non-conformity occurred.

Non-Conformity Fields	Description
Pass Rate	Pass rates only apply to non-conformities found as
	a result of random surveillance. The numerator for
	the pass rate is the number of sites for each
	criterion that passed randomized surveillance for
	the Health IT module being evaluated. The
	denominator is the total number of sites for which
	randomized surveillance was conducted on the
	Health IT module.
Resolution	A detailed description of how the non-conformity
	was resolved.



#### Understanding Certification Status in the CHPL

#### **Product Status**

The CHPL indicates the certification status for each product listed. Not all product listings may have an active certification status. In addition, a product listing without an active certification status may still be eligible for the CMS Quality Payment Program or Promoting Interoperability (PI) Programs. If your product has lost its certification status and you are uncertain as to whether it can be used for the CMS PI Programs, please go to <a href="https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/PaymentAdj">https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/PaymentAdj</a> Hardship.html.

A health IT product listing on the CHPL may have one of the following certification statuses:

Certification	Certification Status	Description
Status Type		
	Active	The product remains certified and in good standing.
Active Certificate	Suspended by ONC	The certification of the product has been suspended by ONC because: (1) ONC believes the product poses a potential risk to public health or safety; (2) the developer fails to timely respond to any communication to ONC, including, but not limited to: fact- finding, a notice of potential non-conformity, or a notice of conformity; (3) the developer fails to timely submit a proposed CAP that adequately addresses the elements required by ONC; or (4) the developer does not fulfill its obligations under the CAP. While the product remains certified, the developer will be unable to update or certify new products for the duration of the suspension.
	Suspended by ONC- ACB	The certification of the product has been suspended by the ONC- ACB due to failure to submit or complete a CAP in time. The product is still considered certified, but it is at risk of having its certification withdrawn.
	Terminated by ONC	The certification of the product has been terminated by ONC. It is no longer considered certified.
Decertified Certificate	Withdrawn by Developer Under Surveillance/Review	The certification of the product has been withdrawn by the product's developer while the product was under ONC-ACB surveillance or ONC direct review. It is no longer considered certified. <i>Note</i> : A certified product withdrawn this way may trigger a certification ban.
	Withdrawn by ONC- ACB	The certification of the product has been withdrawn by the ONC- ACB. It is no longer considered certified.

Certification Status Type	Certification Status	Description
Inactive	Withdrawn by Developer	The certification of the product has been withdrawn by the product's developer because the developer no longer supports the product or for other reasons not in response to ONC-ACB surveillance, ONC direct review, or a finding of non-conformity. It is no longer considered certified.
Certificate	Retired	The product's certification has been retired as part of HHS policy. It is no longer certified. <i>Note</i> : Retired products cannot be used to generate a CMS EHR Certification ID and will not be visible on the CHPL unless searched for under the "Certification Status = Retired" filter.

### **Developer Status**

In accordance with ONC's Enhanced Oversight and Accountability Final rule, two new 'Developer Status' values have been added to the CHPL. The available 'Developer Status' values are now defined as follows:

Developer Status	Description	
Active	Developer has no certified products that are suspended or terminated by ONC. The developer's certificates are in good standing.	
Suspended by ONC	A developer has had one or more of its certified products suspended by ONC per 170.580(d). When a developer has been suspended by ONC, no changes to any of the developer's details, products, versions, or certified products may be made on the CHPL until ONC has lifted the suspension.	
Under Certification Ban by ONC	The health IT developer is precluded from certifying any health IT products under the ONC Health IT Certification Program. A developer may fall under a certification ban if any of the following occurs with their certified products:  (1) Terminated by ONC under the ONC Health IT Certification Program;  (2) Withdrawn from the ONC Health IT Certification Program by an ONC-ACB because the health IT developer requested it to be withdrawn when the health IT developer's health IT was the subject of a potential non-conformity or non-conformity as determined by ONC;  (3) Withdrawn by an ONC-ACB because of a non-conformity with any of the certification criteria adopted by the Secretary under subpart C of part 170 (i.e., Certification Criteria for Health Information Technology); or  (4) Withdrawn by an ONC-ACB because the health IT developer requested it to be withdrawn when the health IT developer's health IT was the subject of surveillance for a certification criterion or criteria adopted by the Secretary under subpart C of part 170, including notice of pending surveillance (e.g., the health IT developer received notice of pending randomized surveillance).	



# Understanding the Safety-Enhanced Design (SED) Criterion (§170.314 (g)(3) and §170.315 (g)(3))

This section is only populated in the CHPL for products that have certified to criteria §170.314 (g)(3)<sup>2</sup> or §170.315 (g)(3). It contains detailed information about how required certification criteria were tested for user-centered design processes. Further information about the regulatory information and test procedures for SED can be found here: https://www.healthit.gov/test-method/safety-enhanced-design.

#### Full Usability Report

Contains a link to the complete usability testing report submitted by the developer to the ONC-ACB.

#### Description of Intended Users

This is a free text section that allows the developer to describe the types of users/health care providers that the product's user-centered design is intended for.

# SED Tested Certification Criteria & Associated User-Centered Design (UCD) Processes

Contains a list of the certification criteria that were tested for SED and which UCD processes were implemented for those criteria. Unless otherwise stated, the UCD process is the same for all criteria listed. This section includes the following:

- Certification Criteria the certification criteria under which the UCD process(es) was applied and tested.
- UCD Process the UCD process(es) applied to the certification criteria.
- UCD Process Details details about the UCD process(es). If a non-standard UCD process was
  used in development, the health IT developer must report the process(es), provide an outline of
  the process(es), a short description of the process(es), and an explanation of the reason(s) why
  use of any of the existing UCD standards was impractical for each required/applicable capability
  presented for certification.

#### **SED Testing Tasks**

Contains a list of tasks upon with UCD processes were tested.

- Description a description of the task tested.
- Task Rating and Scale Type the score the task received from testing and the scoring methods used to evaluate it.
- Details [button] Further details about how the task was scored. Includes the following:

<sup>&</sup>lt;sup>2</sup> 2014 Edition products certified before April 1, 2016, may not have this data available in structured formats on the CHPL because they were certified before this version of the CHPL went live. In addition, the reporting requirements for 2014 Edition products do not require all of the SED testing data to be reported in a structured format, so this part of the CHPL may not be as complete as it is for 2015 Edition products. Regardless, all data on SED testing can be found in the Usability Testing Reports.

February 15, 2019



- Task Description
- Associated Certification Criteria
- Rating Scale
- o Task Rating
- Task Rating Standard Deviation
- o Task Time Mean (s)
- Task Time Standard Deviation (s)
- Task Time Deviation Observed/Optimal (s)
- Task Success Mean (%)
- Task Success Standard Deviation (%)
- Task Errors Mean (%)
- Task Errors Standard Deviation (%)
- Task Path Deviation Observed/Optimal (# of Steps)
- o Total Number of Participants
- o [Participants] Occupation Breakdown
- [Participants] Product Experience Mean (Months)
- o [Participants] Details

#### **Understanding CHPL Shortcut Pages**

#### API Information for 2015 Edition Products Page

This page is found by clicking the button called "API Info for 2015 Ed. Products" on the homepage of the CHPL site or the link under the "Shortcuts" menu on the top menu bar in the top right-hand corner. This page includes all listings on the CHPL that have certified to one of the API criteria ( $\S170.315$  (g)(7), (g)(8), or (g)(9)). It also includes links to a listing's API documentation and mandatory disclosures.

In the upper right-hand side of the page is the API Documentation Data document that contains the API syntax and authorization standard used for all 2015 Edition certified APIs based on a manual review of a developer's API documentation by ONC. The "Download API Documentation Data" button allows the user the ability to download the API Documentation Data. The document's last updated date is displayed under the download button.

This page includes the following information:

- Developer = Name of the product's developer
- Product = Name of the product
- Version = Version of the product
- CHPL ID = The product's unique CHPL ID
- API Documentation = Application access criteria certified to and link to API documentation
- Mandatory Disclosures URL = Link to product's mandatory disclosure required under §170.523 (k)(1)

#### Banned Developers Page

The *Banned Developers* page is found by clicking the button called "Banned Developers" on the homepage of the CHPL site or the link under the "Shortcuts" menu on the top menu bar in the top right-hand corner. This page includes a list of developers precluded from certifying any health IT products under the ONC Health IT Certification Program – including new products as well as upgraded versions of current products. In addition, when a developer has been banned, no changes to any of the developer's details or certified products may be made on the CHPL unless ONC has rescinded the termination determination.

A developer may fall under a certification ban if any of the following occurs with their certified products:

- Terminated by ONC under the ONC Health IT Certification Program (Program);
- (2) Withdrawn from the Program by an ONC-ACB because the health IT developer requested it to be withdrawn when the health IT developer's health IT was the subject of a potential non-conformity or non-conformity as determined by ONC;
- (3) Withdrawn by an ONC-ACB because of a non-conformity with any of the certification criteria adopted by the Secretary under subpart C of part 170 (i.e., Certification Criteria for Health Information Technology); or
- (4) Withdrawn by an ONC-ACB because the health IT developer requested it to be withdrawn when the health IT developer's health IT was the subject of surveillance for a certification criterion or criteria adopted by the Secretary under subpart C of part 170, including notice of pending surveillance (e.g., the health IT developer received notice of pending randomized surveillance).

This page includes the following information:

- Developer = Name of the product's developer
- Date = Date of the Ban
- ONC-ACB = Name of the ONC-ACB that issued the certificate for the product

#### Charts Page

The Charts page is found by clicking the button called "Charts" on the homepage of the CHPL site or the link under the "Shortcuts" menu on the top menu bar in the top right-hand corner. This page has several sections of charts that each have their own set of different types of charts that display the data from several areas of the listings on CHPL. A few examples of the types of sections are Unique Products, Developers, SED Participant, and Nonconformities. Under each section, there are types of graphs such as a bar graph displaying the total number of unique products per criteria, pie charts to display the percentages of new developers for 2015 Edition compared to incumbent developers from 2014 Edition, and a bar graph showing the total number of non-conformities per certification criteria and program requirements.

#### Decertified Products Page

The *Decertified Products* page is found by clicking the button called "Decertified Products" on the homepage of the CHPL site or the link under the "Shortcuts" menu on the top menu bar in the top right-hand corner. This page includes all listings on the CHPL that have had their status changed to a "decertified" status. This page includes listings with any of the following certification statuses:

- Withdrawn by ONC-ACB: The listing's certification was withdrawn by the developer's ONC-ACB.
   These listings are no longer considered a certified product.
- Withdrawn by Developer Under Surveillance/Review: The listing's certification was withdrawn by the developer while the product was under ONC-ACB surveillance or ONC direct review. These listings are no longer considered a certified product.
- **Terminated by ONC:** The listing's certification has been terminated by ONC under the ONC Health IT Certification Program. These listings are no longer considered a certified product.

This page includes the following information:

- Edition = Certification Edition of the product (i.e. 2014, 2015)
- Developer = Name of the product's developer
- Product = Name of the product
- Version = Version of the product
- [Decertification] Date = Date the product was no longer certified
- # of Known Users = Number of known users according to data from the CMS Medicare
   Promoting Interoperability Programs
- ONC-ACB = Name of the ONC-ACB that issued the certificate for the product
- CHPL ID = The product's unique CHPL ID
- Status = Certification status of the product

#### Inactive Certificates Page

The *Inactive Certificates* page is found by clicking the button called "Inactive Certificates" on the homepage of the CHPL site or the link under the "Shortcuts" menu on the top menu bar in the top right-hand corner. This page includes all listings on the CHPL that have had their status changed to an "inactive" status (excluding Retired products). This page includes listings with the following certification status:

Withdrawn by Developer: The listing's certification was withdrawn by the developer. This may
be simply because the developer no longer supports the product or for other reasons that are
not in response to ONC-ACB surveillance, ONC direct review, or a finding of non-conformity.
These listings are no longer considered a certified product.

This page includes the following information:

- Edition = Certification Edition of the product (i.e. 2014, 2015)
- Developer = Name of the product's developer
- Product = Name of the product
- Version = Version of the product
- Inactive As Of = Date the product was no longer certified
- # of Known Users = Number of known users according to data from the CMS Medicare Promoting Interoperability Programs
- ONC-ACB = Name of the ONC-ACB that issued the certificate for the product
- CHPL ID = The product's unique CHPL ID

# Products: Corrective Action Page (Products for which a Non-conformity has been Recorded)

This page is found by clicking the button called "Products: Corrective Action" on the homepage of the CHPL site or under the "Shortcuts" link on the top menu bar in the top right-hand corner. This page includes all listings on the CHPL that have had at least one non-conformity ever recorded. It also includes the number of open and closed non-conformities for the listing.

This page includes the following information:

- Edition = Certification Edition of the product (i.e., 2014, 2015)
- Developer = Name of the product's developer
- Product = Name of the product
- Version = Version of the product
- CHPL ID = The product's unique CHPL ID
- ONC-ACB = Name of the ONC-ACB that issued the certificate for the product
- # Open NCs = Number of non-conformities still under review by ONC or an ONC-ACB for the listing
- # Closed NCs = Number of non-conformities resolved through corrective action or removal of certification status for failure of correction action for the listing



#### SED Information for 2015 Edition Products Page

This page is found by clicking the button called "SED Info for 2015 Ed. Products" on the homepage of the CHPL site or under the "Shortcuts" link on the top menu bar in the top right-hand corner. This page includes all listings on the CHPL that have certified to the Safety-Enhanced Design criterion (§170.315 (g)(3)). It provides a link to view all of a particular listing's SED information in one screen.

This page includes the following information:

- Developer = Name of the product's developer
- Product = Name of the product
- Version = Version of the product
- CHPL ID = The product's unique CHPL ID
- Details = Button to view all of the details of the listing's SED Information

#### Transparency Attestations Page (Certified Health IT Developer Transparency)

This page is found by clicking the button called "Transparency Attestation" on the homepage of the CHPL site or under the "Shortcuts" link on the top menu bar in the top right-hand corner. This page includes a list of all health IT developers on the CHPL and their response to meeting the transparency disclosures and attestation requirements under §170.523 (k)(1) and (k)(2).

This page includes the following information:

- Developer = Name of the product's developer
- Attestation = Developer's response to the Transparency Attestation
- Disclosure URL(s) = Link to developer's mandatory disclosure statement



#### How to Register for an API Key

The CHPL allows users to access CHPL data through application program interfaces (API). In order to use the CHPL APIs, a user must first register for them on the CHPL website.

- 1. Navigate to the CHPL website: <a href="https://chpl.healthit.gov">https://chpl.healthit.gov</a>
- 2. Click the "CHPL Resources" menu on the top menu bar in the top right-hand corner.
- 3. Under the CHPL Resources menu, select "CHPL API."
- 4. Under the Registration box, enter the name or organization and provide an email address.
- 5. Click the green "Register" button.
- 6. The website will display an API key. An email with the unique key assigned to the user will be sent to the email address provided.

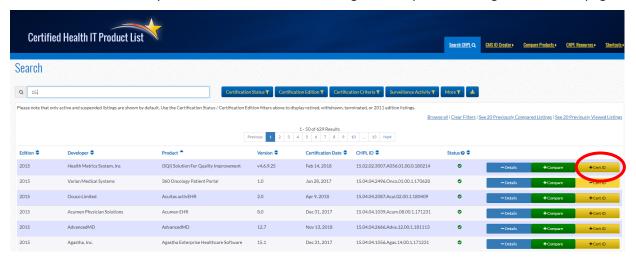
*Note*: Additional documentation for the APIs is provided on the CHPL API page.



#### CMS EHR Certification ID Creation

#### How to Create a CMS EHR Certification ID

- 1. Navigate to the CHPL website: https://chpl.healthit.gov
- 2. Filter the search results for the product(s) that will be used to create the CMS EHR Certification ID
- 3. To add the product(s) that are in the search results, there are two options:
  - a. Click the yellow "+CertID" button to the right of the product listing on the search page;



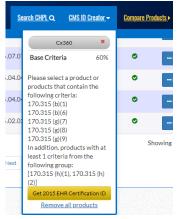
OR

b. Click the blue "\*\*\*Details" button to see the product details page of the listing and then click the yellow "+CertID" button in the right-hand side of the screen.

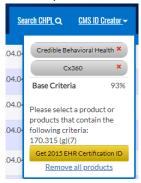


4. Once the product is added, the 'CMS ID Creator' widget, between the "CHPL Search" and "Compare Products" tabs at the top menu bar in the top right-hand corner of the site, will expand showing the product name and current status. Note: You can minimize or maximize this widget by clicking CMS ID Creator.' Additionally, the 'CMS ID Creator' widget will give you information about what is needed in a product to meet the Base EHR requirement (and the CQM requirement for the 2014 Edition Certification ID or the 2014/2015 Certification ID) and allow you to generate a CMS EHR Certification

ID.



5. As additional products are added to the collection, the percentage for the Base Criteria (and the CQM requirement for the 2014 Edition Certification ID or the 2014/2015 Certification ID) and the information related to what information in a product is still needed will update accordingly.



*Note*: The certification edition will change contextually based on the products selected:

- If only 2014 edition products are selected, the 'CMS ID Creator' widget will generate a 2014
   Edition Certification ID
- If only 2015 edition products are selected, the 'CMS ID Creator' widget will generate a 2015
   Edition Certification ID
- If a combination of 2014 and 2015 Edition products are selected, the 'CMS ID Creator' widget will generate a 2014/2015 hybrid Certification ID
- 6. Once you have entered all of the desired products and have met 100% of the Base Criteria (and the appropriate CQM requirement for the 2014 Edition Certification ID or the 2014/2015 Certification ID), you will be able to generate a CMS EHR Certification ID.
- 7. Click the yellow "Get 201[4/5] EHR Certification ID" to generate the CMS EHR Certification ID which corresponds to the selected products. *Note:* If you are unable to click the yellow button, the Base Criteria has not been met yet.



*Note*: Check with the CMS Promoting Interoperability Programs (<a href="https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/index.html">https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/index.html</a>) or other CMS programs that may require a certification ID to confirm which is appropriate for you.

Note: Some withdrawn or terminated certified products may still be used to generate CMS EHR Certification IDs: <a href="https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/FAQ.html">https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/FAQ.html</a>. In these cases, you may need to search for your product using the "Certification Status" filter. Please contact CMS (<a href="mailto:EHRinquiries@cms.hhs.gov">EHRinquiries@cms.hhs.gov</a>) for any questions or concerns regarding whether your product with a withdrawn or terminated certification status is still eligible for the program.

8. Once the CMS EHR Certification ID is generated, it will be displayed in the CHPL widget. Additionally, an option to download the ID in a PDF which can be saved or printed as required will be presented

as well.



9. Once the PDF is downloaded, it will be saved to the default download location. Once opened, the PDF will display the details of the products added into your selection, and the CMS EHR Certification ID will be prominently displayed at the top.

#### **Certified Health IT Product List**

The CMS EHR Certification ID shown corresponds to the collection of products listed below. Submit this ID as part of the attestation process for the CMS EHR Incentive Programs.

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

#### CMS EHR ID: 0015EDU5MAX7XT3

Listing 1		
Certifying Body	ICSA Labs	
Practice Type	N/A	
Product Certification #	15.07.07.2706.CU01.01.00.1.170705	
Developer	CureMD.com, Inc.	
Product Name	CureMD SMART Cloud	
Version	10g	
Classification	N/A	
Certification Edition	2015	
Relied Upon Software Required		



#### How to Look Up a CMS EHR Certification ID

- 1. Navigate to the CHPL website: <a href="https://chpl.healthit.gov">https://chpl.healthit.gov</a>
- 2. Click the "CHPL Resources" menu on the top menu bar in the top right-hand corner.
- 3. Under the CHPL Resources menu, select "CMS ID Reverse Lookup."
- 4. Enter the CMS EHR Certification ID(s) to be pulled up under "Lookup CMS EHR Certification IDs" and click the search (magnifying glass icon) button.
  - a. IDs can be separated by spaces, commas, or semi-colons.
- 5. Click the green "Download Results" button at the bottom of the list to download the full list of certified products as a comma delimited (csv) file.

