

March 2025

This document summarizes the changes to the ONC certification criteria for health IT requirements as outlined in the ONC <u>Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Final Rule</u>. This document was created to provide a general overview of the changes; however, it should not be used as a comprehensive reference document.

For additional information about individual criteria and associated standards, functionalities, and requirements, please click on the provided links for Certification Companion Guides and Conformance or Test Methods.

Health IT Modules are not required to certify to all the criteria listed below and therefore may not be subject to all update requirements. For additional guidance, please consult the HTI-1 Final Rule, ONC Certification Criteria for Health IT Test Procedures and/or Certification Companion Guides. ONC also encourages all Heath IT developers to work with their ONC- Authorized Certification Bodies (ONC-ACBs) to be fully compliant with the ONC Health IT Certification Program.

(No Change)	§ 170.315(a)(1) Computerized provider order entry (CPOE) - medications
Actions to Be Taken	Certified Health IT developers do not need to take any new action for this criterion to maintain compliance with the ONC Health IT Certification Program.
(No Change)	§ 170.315(a)(2) CPOE - laboratory
Actions to Be Taken	Certified Health IT developers do not need to take any new action for this criterion to maintain compliance with the ONC Health IT Certification Program.
(No Change)	§ 170.315(a)(3) CPOE - diagnostic imaging
Actions to Be Taken	Certified Health IT developers do not need to take any new action for this criterion to maintain compliance with the ONC Health IT Certification Program.
(No Change)	§ 170.315(a)(4) Drug-drug, drug-allergy interaction checks for CPOE
Actions to Be Taken	Certified Health IT developers do not need to take any new action for this criterion to maintain compliance with the ONC Health IT Certification Program.



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(Revised)	§ 170.315(a)(5) Patient demographics and observations
References	Certification Companion Guide Conformance Method
Revision to Criterion	Update to the code sets related to race and ethnicity. Update to the code sets referenced related to sex.
Deadline	December 31, 2025
Actions to Be Taken	Health IT developers must attest to updating their criterion to reflect the updated versions of several minimum standard code sets as outlined in regulation, including support for required code sets for previously required data elements and new data elements Sex Parameter for Clinical Use and Pronouns. These regulatory code sets represent the floor for what developers must use in their products. Newer versions of these code sets are permissible for use. Developers must attest to providing functionality to record at least one preferred name to use.
Code Sets to Update	 Race and Ethnicity: § 170.207(f)(2) CDC Race and Ethnicity Code Set Version 1.0 (March 2000) to be updated to § 170.207(f)(3) CDC Race and Ethnicity Code Set Version 1.2 (July 15, 2021) Sex: § 170.207(n)(1) (Birth sex must be coded in accordance with HL7[®] Version 3 Standard, Value Sets for AdministrativeGender and NullFlavor) to be updated to § 170.207(n)(2) Sex must be coded in accordance with SNOMED CT[®] U.S. Edition codes 248152002 [Female (finding)]; and 248153007 [Male (finding)].)
(Time- Limited)	§ 170.315(a)(9) Clinical decision support
References	Certification Companion Guide Conformance Method
Revisions to Criterion	Added to the Base EHR definition until the criterion expires.
Time-limited Certification Until	December 31, 2024, to assist developers' transition to the new certification criterion § 170.315(b)(11) Decision support interventions. Removed from Base EHR definition on expiration date.
Actions to Be Taken	Certified Health IT developers do not need to take any action for this criterion to be compliant with the ONC Health IT Certification Program. ONC-ACBs are permitted to certify to this criterion until December 31, 2024. Developers seeking certification to the Base EHR definition must update to the "decision support interventions" certification criterion in § 170.315(b)(11).



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(Revised)	§ 170.315(a)(12) Family health history
References	Certification Companion Guide Conformance Method
Revision to Criterion	Update to the code sets referenced related to problems to reflect newer SNOMED CT® version.
Deadline	December 31, 2025
Actions to Be Taken	Health IT developers must attest to updating their criterion to reflect the minimum standard code sets for problems as outlined in regulation. These regulatory code sets represent the floor for what developers must use in their products. Newer versions of these code sets are permissible for use.
Code Sets to Update	§ 170.207(a)(4) SNOMED CT [®] , U.S. Edition, September 2015 Release to be updated to § 170.207(a)(1) SNOMED CT [®] , U.S. Edition, March 2022 Release
(No Change)	§ 170.315(a)(14) Implantable device list
Actions to Be Taken	Certified Health IT developers do not need to take any new action for this criterion to maintain compliance with the ONC Health IT Certification Program.
(Revised)	§ 170.315(a)(15) Social, psychological, and behavior data
References	Certification Companion Guide Conformance Method
Revision to Criterion	Update to the code sets referenced to reflect newer LOINC [®] and Unified Code of Units of Measure (UCUM) standards
Deadline	December 31, 2025
Actions to Be Taken	 The Health IT developer attests to the updated code sets. The ONC-ACB validates completeness of the attestation and updates the CHPL listing to include certification to the updated requirements.

Data elements outlined in the criteria must be coded in accordance with the updates to the LOINC® and UCUM standards below:

Code Sets to § 170.207(c)(3) LOINC[®] Database version 2.52 to be updated to § 170.207(c)(1) LOINC[®], Database Version 2.72, February 16, 2022 § 170.207(m)(1) The Unified Code for Units of Measure, Revision 1.9 to be updated to § 170.207(m)(2)

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Update



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(Revised)	§ 170.315(b)(1) Transitions of care
References	Certification Companion Guide Test Procedure
Revision to Criterion	Update to the United States Core Data for Interoperability (USCDI) and Consolidated Clinical Document Architecture (C-CDA) Companion Guide. The USCDI replaces version 1 with version 3. Refer to the <u>USCDI</u> <u>CCG</u> for a list of new required data classes and elements for USCDI v3. Updates to the minimum standard code sets outlined for Problems and Sex Constraint.
Deadline	December 31, 2025
Actions to Be Taken	 The Health IT developer attests to the updated USCDI/C-CDA requirements to the ONC-ACB. The Health IT developer attests to the updated code sets requirements. The ONC-ACB validates completeness of the attestation and updates the CHPL listing to include certification to the updated requirements.
Standards/Code Sets to Update	 USCDI version 1 (v1) (July 2020 Errata) to be updated to USCDI version 3 (v3) HL7® C-CDA® R2 Implementation Guide: C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 2 to be updated to C-CDA R2 IG Companion Guide, Release 4.1 § 170.207(a)(4) SNOMED CT®, U.S. Edition, September 2015 Release to be updated to § 170.207(a)(1) SNOMED CT®, U.S. Edition, March 2022 Release § 170.207(n)(1) Birth sex must be coded in accordance with HL7® Version 3 Standard, Value Sets for AdministrativeGender and NullFlavor to be updated to § 170.207(n)(2) Sex must be coded in accordance with SNOMED CT® U.S. Edition codes 248152002 Female (finding) ; and 248153007 Male (finding) .

(Revised)	§ 170.315(b)(2) Clinical information reconciliation and incorporation
References	Certification Companion Guide Test Procedure
Revision to Criterion	Update to the United States Core Data for Interoperability (USCDI) and Consolidated Clinical Document Architecture (C-CDA) Companion Guide. The USCDI replaces version 1 with version 3. Refer to the end of this document for a list of new required data classes and elements for USCDI v3.
Deadline	December 31, 2025
Actions to Be Taken	 The Health IT developer attests to the updated requirements to the ONC-ACB. The ONC-ACB validates completeness of the attestation and updates the CHPL listing to include certification to the updated requirements.
Standards/Code Sets to Update	 USCDI version 1 (v1) (July 2020 Errata) to be updated to USCDI version 3 (v3) HL7[®] C-CDA[®] R2 Implementation Guide: C–CDA Templates for Clinical Notes R2.1 Companion Guide, Release 2 to be updated to C-CDA R2 IG Companion Guide, Release 4.1



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(Revised)	§ 170.315(b)(3) Electronic prescribing
References	Certification Companion Guide Test Procedure
Revision to Criterion	Update medication code sets to reference the RxNorm, July 5, 2022 Full Monthly Release.
Deadline	December 31, 2025
Actions to Be Taken	 The Health IT developer attests to the updated requirements to the ONC-ACB. The ONC-ACB validates completeness of the attestation and updates the CHPL listing to include certification to the updated requirements.
Code Sets to Update	§ 170.207(d)(3) RxNorm, September 8, 2015 Full Release Update to be updated to § 170.207(d)(1) RxNorm, July 5, 2022 Full Monthly Release

(No Change)	§ 170.315(b)(7) Security tags - summary of care—send
Actions to Be Taken	Certified Health IT developers do not need to take any new action for this criterion to maintain compliance with the ONC Health IT Certification Program.

(No Change)	§ 170.315(b)(8) Security tags - summary of care—receive
Actions to Be Taken	Certified Health IT developers do not need to take any new action for this criterion to maintain compliance with the ONC Health IT Certification Program.

(Revised)	§ 170.315(b)(9) Care plan
References	Certification Companion Guide Test Procedure
Revision to Criterion	Update to the Consolidated Clinical Document Architecture (C-CDA) Companion Guide.
Deadline	December 31, 2025
Actions to Be Taken	 The Health IT developer attests to the updated requirements to the ONC-ACB. The ONC-ACB validates completeness of the attestation and updates the CHPL listing to include certification to the updated requirements.
Standards to Update	HL7 [®] C-CDA [®] R2 Implementation Guide: C–CDA Templates for Clinical Notes R2.1 Companion Guide, Release 2 to be updated to C-CDA R2 IG Companion Guide, Release 4.1



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(No Change)	§ 170.315(b)(10) Electronic Health Information (EHI) export
Actions to Be Taken	Certified Health IT developers do not need to take any new action for this criterion to maintain compliance with the ONC Health IT Certification Program.
(New)	§ 170.315(b)(11) Decision support interventions (DSI)
References	Certification Companion Guide Conformance Method
New Criterion Requirements	 Added to the Base EHR definition. Building upon the requirements outlined CDS criterion in § 170.315(a)(9), a Certified Health IT Module certifying to the DSI criterion must: Enable end users to provide electronic feedback based on information displayed and make available such feedback data for export. Enable a user to review plain language descriptions of source attribute information. Updates the list of source attributes that must be included for evidence-based decision support interventions and predictive decision support interventions
Deadline	A health IT developer seeking to meet the Base EHR definition requirements must add this to a Health IT Module by December 31, 2024.
Actions to Be Taken	 The Health IT developer attests to the updated requirements to the ONC-ACB. The ONC-ACB validates completeness of the attestation and updates the CHPL listing to include certification to the updated requirements.
Additional Dependencies for	The Health IT developer must conduct summative usability testing and submit documentation to their ONC-ATL, consistent with the Test Procedure identified with § 170.315(g)(3), in order to be fully

(No Change)	§ 170.315(c)(1) Clinical quality measures - record and export
Actions to Be Taken	Certified Health IT developers do not need to take any new action for this criterion to maintain compliance with the ONC Health IT Certification Program.
(No Change)	§ 170.315(c)(2) Clinical quality measures - import and calculate
Actions to Be Taken	Certified Health IT developers do not need to take any new action for this criterion to maintain compliance with the ONC Health IT Certification Program.
(No Change)	§ 170.315(c)(3) Clinical quality measures - report
Actions to Be Taken	Certified Health IT developers do not need to take any new action for this criterion to maintain compliance with the ONC Health IT Certification Program.

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Certification



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(Revised)	§ 170.315(c)(4) Clinical quality measures (CQMs) - filter
References	Certification Companion Guide Test Procedure
Revision to Criterion	Update to the code sets referenced related to provider type, patient insurance, patient sex, race and ethnicity and patient problem list data
Deadline	December 31, 2025
Actions to Be Taken	 The Health IT developer attests to the updated minimum standard code set requirements to the ONC-ACB. The ONC-ACB validates completeness of the attestation and updates the CHPL listing to include certification to the updated requirements.
	 § 170.207(f)(2) CDC Race and Ethnicity Code Set Version 1.0 (March 2000) to be updated to § 170.207(f)(3) CDC Race and Ethnicity Code Set Version 1.2 (July 15, 2021)
Code Sets to Update	 § 170.207(a)(4) SNOMED CT[®], U.S. Edition, September 2015 Release to be updated to § 170.207(a)(1) SNOMED CT[®], U.S. Edition, March 2022 Release
	 § 170.207(r)(1) Crosswalk: Medicare Provider/Supplier to Healthcare Provider Taxonomy, April 2, 2015 to be updated to § 170.207(r)(2) Medicare Provider and Supplier Taxonomy Crosswalk, October 29, 2021
	 § 170.207(s)(1) Public Health Data Standards Consortium Source of Payment Typology Code Set Version 5.0 (October 2011) to be updated to § 170.207(s)(2) Public Health Data Standards Consortium Source of Payment Typology Code Set, December 2020, Version 9.2
	 § 170.207(n)(1) Birth sex must be coded in accordance with HL7[®] Version 3 Standard, Value Sets for AdministrativeGender and NullFlavor to be updated to § 170.207(n)(2) Sex must be coded in accordance with SNOMED CT[®] U.S. Edition codes 248152002 Female (finding) ; and 248153007 Male (finding) .
(No Change)	§ 170.315(d)(1) Authentication, access control, authorization
Actions to Be Taken	Certified Health IT developers do not need to take any new action for this criterion to maintain compliance with the ONC Health IT Certification Program.
(Revised)	§ 170.315(d)(2) Auditable events and tamper-resistance

References	Certification Companion Guide Conformance Method	
Revision to Criterion	Update to allow Health IT Modules to use any network time protocol (NTP) standard that can ensure a system clock has been synchronized and meets time accuracy requirements, removing reference to a specific standard to provide this functionality.	
Actions to Be Taken	Health IT developers already certified to this criterion do not need to take any action to be compliant with the ONC Health IT Certification Program.	



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(Revised)	§ 170.315(d)(3) Audit report(s)		
References	Certification Companion Guide Conformance Method		
Revision to Criterion	Update to allow Health IT Modules to use any network time protocol (NTP) standard that can ensure a system clock has been synchronized and meets time accuracy requirements, removing reference to a specific standard to provide this functionality.		
Actions to Be Taken	Health IT developers already certified to this criterion do not need to take any action to be compliant with the ONC Health IT Certification Program.		
(No Change)	§ 170.315(d)(4) Amendments		
Actions to Be Taken	Certified Health IT developers do not need to take any new action for this criterion to maintain compliance with the ONC Health IT Certification Program.		
(No Change)	§ 170.315(d)(5) Automatic access time-out		
Actions to Be Taken	Certified Health IT developers do not need to take any new action for this criterion to maintain compliance with the ONC Health IT Certification Program.		
(No Change)	§ 170.315(d)(6) Emergency access		
Actions to Be Taken	Certified Health IT developers do not need to take any new action for this criterion to maintain compliance with the ONC Health IT Certification Program.		
(No Change)	§ 170.315(d)(7) End-user device encryption		
Actions to Be Taken	Certified Health IT developers do not need to take any new action for this criterion to maintain compliance with the ONC Health IT Certification Program.		
(No Change)	§ 170.315(d)(8) Integrity		
Actions to Be Taken	Certified Health IT developers do not need to take any new action for this criterion to maintain compliance with the ONC Health IT Certification Program.		
(No Change)	§ 170.315(d)(9) Trusted connection		
Actions to Be Taken	Certified Health IT developers do not need to take any new action for this criterion to maintain compliance with the ONC Health IT Certification Program.		



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(Revised)	§ 170.315(d)(10) Auditing actions on health information		
References	Certification Companion Guide Conformance Method		
Revision to Criterion	Update to allow Health IT Modules to use any network time protocol (NTP) standard that can ensure a system clock has been synchronized and meets time accuracy requirements, removing reference to a specific standard to provide this functionality.		
Actions to Be Taken	Health IT developers already certified to this criterion do not need to take any action to be compliant with the ONC Health IT Certification Program.		
(No Change)	§ 170.315(d)(11) Accounting of disclosures		
Actions to Be Taken	Certified Health IT developers do not need to take any new action for this criterion to maintain compliance with the ONC Health IT Certification Program.		
(No Change)	§ 170.315(d)(12) Encrypt authentication credentials		
Actions to Be Taken	Certified Health IT developers do not need to take any new action for this criterion to maintain compliance with the ONC Health IT Certification Program.		
(No Change)	§ 170.315(d)(13) Multi-factor authentication (MFA)		
Actions to Be Taken	Certified Health IT developers do not need to take any new action for this criterion to maintain compliance with the ONC Health IT Certification Program.		
(Revised)	§ 170.315(e)(1) View, download, and transmit to 3rd party		
References	Certification Companion Guide Test Procedure		
Revision to Criterion	 Update to the United States Core Data for Interoperability (USCDI) and Consolidated Clinical Document Architecture (C-CDA) Companion Guide. The USCDI replaces version 1 with version 3. Refer to the end of this document for a list of new required data classes and elements for USCDI v3. Additional functionality requirement to ensure patients can request restrictions to any data expressed in USCDI. Update to allow Health IT Modules to use any network time protocol (NTP) standard that can ensure a system clock has been synchronized and meets time accuracy requirements, removing reference to a specific standard to provide this functionality. 		
Deadline	December 31, 2025		
Actions to Be Taken	 The health IT developer attests to the updated USCDI/C-CDA and functionality requirements to the ONC-ACB. The ONC-ACB validates completeness of the attestation and updates the CHPL listing to include certification to the updated requirements. Health IT developers do not need to take any action related to the updated NTP requirements. 		
Standards to Update	 USCDI version 1 (v1) (July 2020 Errata) to be updated to USCDI version 3 (v3) HL7[®] C-CDA R2 Implementation Guide: C–CDA Templates for Clinical Notes R2.1 Companion Guide, Release 2 to be updated to C-CDA R2 IG Companion Guide, Release 4.1 		



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(No Change)	§ 170.315(e)(3) Patient health information capture		
Actions to Be Taken	Certified Health IT developers do not need to take any new action for this criterion to maintain compliance with the ONC Health IT Certification Program.		
(Revised)	§ 170.315(f)(1) Transmission to immunization registries		
References	Certification Companion Guide Test Procedure		
Revision to Criterion	Update to the code sets referenced related to historical vaccines and administered vaccines.		
Deadline	December 31, 2025		
Actions to Be Taken	 The Health IT developer attests to the updated requirements to the ONC-ACB. The ONC-ACB validates completeness of the attestation and updates the CHPL listing to include certification to the updated requirements. 		
Code Sets to Update	 § 170.207(e)(3) HL7[®] Standard Code Set CVX—Vaccines Administered, updates through August 17, 2015 to be updated to § 170.207(e)(1) HL7[®] Standard Code Set CVX - Vaccines Administered, updates through June 15, 2022 § 170.207(e)(4) National Drug Code Directory (NDC)—Vaccine NDC Linker, updates through August 17, 2015 to be updated to § 170.207(e)(2) National Drug Code Directory (NDC) - Vaccine NDC Linker, updates through July 19, 2022 		
(No Change)	§ 170.315(f)(2) Transmission to public health agencies - syndromic surveillance		
Actions to Be Taken	Certified Health IT developers do not need to take any new action for this criterion to maintain compliance with the ONC Health IT Certification Program.		
(Revised)	§ 170.315(f)(3) Transmission to public health agencies - reportable laboratory tests and values/results		
References	Certification Companion Guide Test Procedure		
Revision to Criterion	Update to the versions of SNOMED CT [®] and LOINC [®] specified in the criterion.		
Deadline	December 31, 2025		
Actions to Be Taken	 The Health IT developer attests to the updated requirements to the ONC-ACB. The ONC-ACB validates completeness of the attestation and updates the CHPL listing to include certification to the updated requirements. 		
Code Sets to Update	 § 170.207(a)(3) HTSDO SNOMED CT[®] International Release July 2012 and US Extension to SNOMED CT[®] March 2012 Release to be updated to § 170.207(a)(1) SNOMED CT[®], U.S. Edition, March 2022 Release § 170.207(c)(2) LOINC[®] Database version 2.40 to be updated to § 170.207(c)(1) LOINC[®], Database Version 2.72, February 16, 2022 		



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(Revised)	§ 170.315(f)(4) Transmission to cancer registries	
References	Certification Companion Guide Test Procedure	
Revision to Criterion	Update to the versions of SNOMED CT [®] and LOINC [®] specified in the criterion.	
Deadline	December 31, 2025	
Actions to Be Taken	 The Health IT developer attests to the updated requirements to the ONC-ACB. The ONC-ACB validates completeness of the attestation and updates the CHPL listing to include certification to the updated requirements. 	
Code Sets to Update	 § 170.207(a)(4) SNOMED CT[®], U.S. Edition, September 2015 Release to be updated to § 170.207(a)(1) SNOMED CT[®], U.S. Edition, March 2022 Release § 170.207(c)(2) LOINC[®] Database version 2.40 to be updated to § 170.207(c)(1) LOINC[®], Database Version 2.72, February 16, 2022 	

(Revised)	§ 170.315(f)(5) Transmission to public health agencies - electronic case reporting		
References	Certification Companion Guide Conformance Method		
Revision to Criterion	Update to the criterion outlining new standards and code sets to meet existing functionality requirements.		
Deadline	December 31, 2025		
Actions to Be Taken	 The Health IT developer attests to the updated requirements to the ONC-ACB. The ONC-ACB validates completeness of the attestation and updates the CHPL listing to include certification to the updated requirements. 		
Standards/Code Sets to Update	 New code sets include: Reportable Conditions Trigger Codes Value Set for Electronic Case Reporting. RCTC OID: 2.16.840.1.114222.4.11.7508 New standards for use include: HL7[®] FHIR[®] Implementation Guide: Electronic Case Reporting (eCR)—US Realm 2.1.0—STU 2 US (HL7[®] FHIR[®] eCR IG) HL7[®] CDA[®] R2 Implementation Guide: Public Health Case Report—the Electronic Initial Case Report (eICR) Release 2, STU Release 3.1—US Realm (HL7[®] CDA eICR IG) HL7[®] CDA[®] R2 Implementation Guide: Reportability Response, Release 1, STU Release 1.1—US Realm (HL7[®] CDA RR IG) 		
(No Change)	§ 170.315(f)(6) Transmission to public health agencies - antimicrobial use and resistance reporting		
Actions to Be Taken	Certified Health IT developers do not need to take any new action for this criterion to maintain compliance with the ONC Health IT Certification Program.		



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(No Change)	§ 170.315(f)(7) Transmission to public health agencies - health care surveys	
Actions to Be Taken	Certified Health IT developers do not need to take any new action for this criterion to maintain compliance with the ONC Health IT Certification Program.	
(No Change)	§ 170.315(g)(1) Automated numerator recording	
Actions to Be Taken	Certified Health IT developers do not need to take any new action for this criterion to maintain compliance with the ONC Health IT Certification Program.	
(No Change)	§ 170.315(g)(2) Automated measure calculation	
Actions to Be Taken	Certified Health IT developers do not need to take any new action for this criterion to maintain compliance with the ONC Health IT Certification Program.	
(Revised)	§ 170.315(g)(3) Safety-enhanced design	
References	Certification Companion Guide <u>Test Procedure</u>	
Revision to Criterion	Added § 170.315(b)(11) Decision support interventions criterion to the list of criteria that must apply user-centered design processes to the capabilities outlined in the criterion.	
Actions to Be Taken	Certified Health IT developers do not need to take any action for this criterion to be compliant with the ONC Health IT Certification Program. Developers seeking certification to § 170.315(b)(11) must complete certification requirements for § 170.315(g)(3) as outlined to meet Certification Program requirements.	
(No Change)	§ 170.315(g)(4) Quality management system	
Actions to Be Taken	Certified Health IT developers do not need to take any new action for this criterion to maintain compliance with the ONC Health IT Certification Program.	
(No Change)	§ 170.315(g)(5) Accessibility-centered design	
Actions to Be Taken	Certified Health IT developers do not need to take any new action for this criterion to maintain compliance with the ONC Health IT Certification Program.	



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(Revised)	§ 170.315(g)(6) Consolidated-CDA creation performance
References	Certification Companion Guide Test Procedure
Revision to Criterion	Update to the United States Core Data for Interoperability (USCDI) and Consolidated Clinical Document Architecture (C-CDA) Companion Guide. The USCDI replaces version 1 with version 3. Refer to the end of this document for a list of new required data classes and elements for USCDI v3.
Deadline	December 31, 2025.
Actions to Be Taken	 The Health IT developer attests to the updated requirements to the ONC-ACB. The ONC-ACB validates completeness of the attestation and updates the CHPL listing to include certification to the updated requirements.
Standards to Update	 USCDI version 1 (v1) (July 2020 Errata) to be updated to USCDI version 3 (v3) HL7® C-CDA® R2 Implementation Guide: C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 2 to be updated to C-CDA R2 IG Companion Guide, Release 4.1

(No Change)	§ 170.315(g)(7) Application access - patient selection	
Actions to Be Taken	Certified Health IT developers do not need to take any new action for this criterion to maintain compliance with the ONC Health IT Certification Program.	
Additional Dependencies for Certification	The Health IT developer must attest to § 170.315(d)(14) Patient requested restrictions in order to be fully compliant with the ONC Health IT Certification Program.	

(Revised)	§ 170.315(g)(9) Application access - all data request		
References	Certification Companion Guide Test Procedure		
Revision to Criterion	Update to the United States Core Data for Interoperability (USCDI) and Consolidated Clinical Document Architecture (C-CDA) Companion Guide. The USCDI replaces version 1 with version 3. Refer to the end of this document for a list of new required data classes and elements for USCDI v3.		
Deadline	December 31, 2025.		
Actions to Be Taken	 The Health IT developer attests to the updated requirements to the ONC-ACB. The ONC-ACB validates completeness of the attestation and updates the CHPL listing to include certification to the updated requirements. 		
Standards to Update	 USCDI version 1 (v1) (July 2020 Errata) to be updated to USCDI version 3 (v3) HL7[®] C-CDA[®] R2 Implementation Guide: C–CDA Templates for Clinical Notes R2.1 Companion Guide, Release 2 to be updated to C-CDA R2 IG Companion Guide, Release 4.1 		



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References	Certification Companion Guide	Test Procedure	
Revision to Criterion	• Health IT Modules must update their patient authorization revocation functionality to be able to revoke access within 1 hour of the request.	 Updated the Maintenance of Certification requirements under § 170.404(b)(2) to indicate a deadline for publication of service base URLs for use by patients to access their electronic health information. Health IT Modules will be required to publish, at no charge, the service base URLs and related organizational details that can be used by patients to access their EHI. 	 Update to the United States Core Data for Interoperability (USCDI). The USCDI replaces version 1 with version 3. Refer to the end of this document for a list of new required data classes and elements for USCDI v3. Health IT Modules must update versions of the SMART Application Launch Frameworn Implementation Guide and HL7[®] FHIR[®] US Core Implementation Guide.
Deadline	Effective Date (March 11, 2024)	December 31, 2024.	December 31, 2025.
Actions to Be Taken	Health IT developers must attest to updating their criterion to address the revised functionality.	Developers must publish, at no charge, the service base URLs and related organization details that can be used by patients to access their electronic health information.	 Developers attest that they have updated their standards and provided them to their customers. ONC-ACBs verify attestation to new updated standards. Once verified, ACBs will update the listing to indicate certification to the required standards.
Standards to Update	Not applicable.	Service-base URLs and related organizational details must be published in a standardized, FHIR [®] -based format.	 USCDI version 1 (v1) (July 2020 Errata) to be updated to USCDI version 3 (v3) SMART Application Launch Framework Implementation Guide Release 1.0.0 to be updated to SMART Application Launch Framework Implementation Guide Release 2.0.0 HL7[®] FHIR[®] US Core Implementation Guide STU 3.1.1 to be updated to HL7[®] FHIR[®] US Core Implementation Guide STU 6.1.0



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(No Change)	§ 170.315(h)(1) Direct Project	
Actions to Be Taken	Certified Health IT developers do not need to take any action for this criterion to be compliant with the ONC Health IT Certification Program.	
(No Change)	§ 170.315(h)(2) Direct Project, Edge Protocol, and XDR/XDM	
Actions to Be Taken	Certified Health IT developers do not need to take any action for this criterion to be compliant with the ONC Health IT Certification Program.	



Disclaimer: This fact sheet describes requirements outlined in the Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) final rule. While every effort has been made to ensure the accuracy of this fact sheet, it is not a legal document. Please refer to the HTI-1 final rule for full provision details.