

2015 Edition Certification Companion Guide

Application Access – All Data Request - 45 CFR 170.315(g)(9)

Links will be updated as available: [Final Rule Preamble](#) – [Test Procedure](#) – [Test Data](#) – [MU Specification Sheet](#)

Version 1.1 – Last Updated 02/05/2016

New/Revised/Unchanged Compared to 2014 Edition	Gap Certification Eligible	Base EHR Definition	In Scope for Certified EHR Technology Definition	Associated EHR Incentive Program Objective(s)
New	No	Yes	Yes	Objective 5 Objective 6

Certification Requirements

Privacy and Security: This certification criterion was adopted at § 170.315(g)(9). As a result, an ONC-ACB must ensure that a product presented for certification to this criterion includes the privacy and security criteria (adopted in § 170.315(d)) within the overall scope of the certificate issued to the product.

- The privacy and security criteria (adopted in § 170.315(d)) do not need to be explicitly tested with this specific criterion unless it is the only criterion for which certification is requested.
- As a general rule, a product presented for certification only needs to be tested once to each applicable privacy and security criterion (adopted in § 170.315(d)) so long as the health IT developer attests that such privacy and security capabilities apply to the full scope of capabilities included in the requested certification. However, exceptions exist for § 170.315(e)(1) “VDT” and (e)(2) “secure messaging,” which are explicitly stated.

Design and Performance: The following design and performance certification criteria (adopted in § 170.315(g)) must also be certified in order for the product to be certified.

- When a single quality management system (QMS) is used, the QMS only needs to be identified once. Otherwise, the QMS’ need to be identified for every capability to which it was applied.
- 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, alternatively the developer must state that no accessibility-centered design was used.
- C-CDA creation performance (§ 170.315(g)(6)) does not need to be explicitly tested with this criterion unless it is the only criterion within the scope of the requested certification that includes C-CDA creation capabilities. Note that the application of § 170.315(g)(6) depends on the C-CDA templates explicitly required by the C-CDA-referenced criterion or criteria included within the scope of the certificate sought. Please refer to the [C-CDA creation performance Certification Companion Guide](#) for more details.

Privacy and Security (§ 170.315(d))	Design and Performance (§ 170.315(g))
<ul style="list-style-type: none"> • If choosing Approach 1: <ul style="list-style-type: none"> ○ Authentication, access control, and authorization (§ 170.315(d)(1)) ○ Trusted connection (§ 170.315(d)(9)) ○ Either auditable events and tamper-resistance (§ 170.315(d)(2)) or auditing actions on health information (§ 170.315(d)(10)). • If choosing Approach 2: <ul style="list-style-type: none"> ○ For each applicable P&S certification criterion not certified for approach 1, the health IT developer may certify for the criterion using system documentation which provides a clear description of how the external services necessary to meet the P&S criteria would be deployed and used. 	<ul style="list-style-type: none"> • Quality management system (§ 170.315(g)(4)) • Accessibility-centered design (§ 170.315(g)(5)) • Consolidated CDA creation performance (§ 170.315(g)(6))

Regulation Text

Application access - all data request. The following technical outcome and conditions must be met through the demonstration of an application programming interface.

(i) Functional requirements.

(A) Respond to requests for patient data (based on an ID or other token) for all of the data categories specified in the Common Clinical Data Set at one time and return such data (according to the specified standards, where applicable) in a summary record formatted according to the standard adopted in § 170.205(a)(4) following the CCD document template.

(B) Respond to requests for patient data associated with a specific date as well as requests for patient data within a specified date range.

(ii) Documentation.

(A) The API must include accompanying documentation that contains, at a minimum:

(1) API syntax, function names, required and optional parameters and their data types, return variables and their types/structures, exceptions and exception handling methods and their returns.

(2) The software components and configurations that would be necessary for an application to implement in order to be able to successfully interact with the API and process its response(s).

(3) Terms of use. The terms of use for the API must be provided, including, at a minimum, any associated developer policies and required developer agreements.

(B) The documentation used to meet paragraph (g)(9)(ii)(A) of this section must be available via a publicly accessible hyperlink.

Criterion Subparagraph	Technical Explanations and Clarifications	Standard(s) Referenced
Applies to entire criterion	<p>Clarifications:</p> <ul style="list-style-type: none"> • Security: <ul style="list-style-type: none"> ○ Our intention is to encourage dynamic registration (e.g., OAuth 2.0 Connect Dynamic Client Registration Protocol) and strongly believe that registration should not be used as a means to block information sharing via APIs. That is, applications should not be required to pre-register (or be approved in advance) with the provider or their Health IT Module developer before being allowed to access the API. Under the 2015 Edition privacy and security (P&S) certification framework, health IT certified to the API criteria must support an application connecting to the API. The P&S certification framework for the API criteria requires that a Health IT Module certified to this criterion be capable of ensuring that: valid user credentials such as a username and password are presented (that match the credentials on file at the provider for that user); the provider can authorize the user to view the patient’s data; the application connects through a trusted connection; and the access is audited (§ 170.515(d)(1); (d)(9); and (d)(2) or (d)(10); respectively). These certification requirements should be sufficient to allow access without requiring further application pre-registration. [see also 80 FR 62676] This criterion does not currently include any security requirements beyond the privacy and security approach detailed above, but we encourage organizations to follow security best practices and implement security controls, such as penetration testing, encryption, audits, and monitoring as appropriate. We expect health IT developers to include information on how to securely use their APIs in the public documentation required by the certification criteria and follow industry best practices. [see also 80 FR 62676] ○ We strongly encourage developers to build security into their APIs following best practice guidance, such as the Department of Homeland Security’s Build Security In initiative.¹ [see also 80 FR 62677] ○ APIs may be used to enable patient access to data in the Designated Record Set for that individual, pursuant to 45 CFR 164.524(a)(1). The electronic tools an individual uses to handle or transport data in the individual’s custody are not required to meet the HIPAA Security Rule. [see also 80 FR 62677] <p style="text-align: right;"><i>Continued on next page</i></p>	N/A

¹ <https://buildsecurityin.us-cert.gov/>

Criterion Subparagraph	Technical Explanations and Clarifications	Standard(s) Referenced
Applies to entire criterion, continued	<p><i>Continued from previous page</i></p> <ul style="list-style-type: none"> ▪ Per 45 CFR 164.501, <i>Designated record set</i> means: (1) A group of records maintained by or for a covered entity that is: (i) The medical records and billing records about individuals maintained by or for a covered health care provider; (ii) The enrollment, payment, claims adjudication, and case or medical management record systems maintained by or for a health plan; or (iii) Used, in whole or in part, by or for the covered entity to make decisions about individuals. ○ APIs could be used when consent or authorization by an individual is required. In circumstances where there is a requirement to document a patient’s request or particular preferences, APIs can enable compliance with documentation requirements. The HIPAA Privacy Rule² permits the use of electronic documents to qualify as writings for the purpose of proving signature, e.g., electronic signatures. [see also 80 FR 62677] • The audit record should be able to distinguish the specific user who accessed the data using a third-party application through the certified API in order to meet the requirements of § 170.515(d)(2) or (d)(10). • A ”third-party API” can be something developed by the vendor for the purposes of meeting testing and certification requirements, including but not limited to a test harness, test tool or product application. • By requiring that documentation and terms of use be open and transparent to the public by requiring a hyperlink to such documentation to be published with the product on the ONC Certified Health IT Product List, we hope to encourage an open ecosystem of diverse and innovative applications that can successfully and easily interact with different Health IT Modules’ APIs. [see also 80 FR 62679] 	N/A

² 45 CFR Part 160 and Part 164, Subparts A and E

Criterion Subparagraph	Technical Explanations and Clarifications	Standard(s) Referenced
(i)(A)	<ul style="list-style-type: none"> Technical outcome – The API must be able to respond to requests for patient data (using an ID or other token) for <u>all</u> of the data categories specified in the Common Clinical Data Set at one time in a summary record formatted according to the Consolidated CDA Release 2.1 Continuity of Care Document (CCD) template. <p>Clarifications:</p> <ul style="list-style-type: none"> Please refer to the 2015 Edition Common Clinical Data Set for the data standards that are required. The technology specifications should be designed and implemented in such a way as to return meaningful responses to queries, particularly with regard to exceptions and exception handling, and should make it easy for applications to discover what data exists for the patient. [see also 80 FR 62678] The term “token” that is used here is not to be interpreted as the token in the OAuth2 workflow, but simply as an identifier for a unique patient ID. 	<p>§ 170.205(a)(4) HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use Release 2.1, August 2015</p> <p>Please refer to the standards required for the 2015 Edition Common Clinical Data Set.</p>
(i)(B)	<ul style="list-style-type: none"> Technical outcome – The API must be able to respond to requests for patient data associated with a specific date as well as with a specific date range. <p>Clarifications:</p> <ul style="list-style-type: none"> Health IT returning an entire patient record that does not reflect the specific date or date range requested is not permissible when a specific date or date range is requested. [see also 80 FR 62678] Additionally, we expect that Health IT must be able to send all required data for a specific date range specified, but we acknowledge that there will be organizational policies / safety best practices that will dictate when records qualify on readiness, and we expect that vendors will employ user-centered design and return information in a way that prioritizes patient preferences and usability. 	N/A
(ii)(A)(1)	<ul style="list-style-type: none"> Technical outcome – The API must include accompanying documentation which contains API syntax, function names, required and optional parameters and their data types, return variables and their types/structures, exceptions and exception handling methods and their returns. <p>Clarifications:</p> <ul style="list-style-type: none"> No additional clarifications available. 	N/A

Criterion Subparagraph	Technical Explanations and Clarifications	Standard(s) Referenced
(ii)(A)(2)	<ul style="list-style-type: none"> Technical outcome – The API must include accompanying documentation, which contains software components and configurations that would be necessary for an application to implement in order to be able to successfully interact with the API and process its response(s). <p>Clarifications:</p> <ul style="list-style-type: none"> No additional clarifications available. 	N/A
(ii)(A)(3)	<ul style="list-style-type: none"> Technical outcome – The API must include the terms of use for the API including, at a minimum any associated developer policies and required developer agreements. <p>Clarifications:</p> <ul style="list-style-type: none"> If Health IT Developers typically execute unique agreements or contracts with interested third party applications using their API, they must disclose that this is a standard practice in their terms of use. Health IT Developers are not required to disclose the actual completed agreements that they establish with third party applications. Instead, they must be clear and transparent about the general terms of such agreements that will typically apply to prospective third party applications. 	N/A
(ii)(B)	<ul style="list-style-type: none"> Technical outcome – The documentation used to meet the provisions in (ii)(A)(1)-(3) must be available through a publicly accessible hyperlink. <p>Clarifications:</p> <ul style="list-style-type: none"> The hyperlink provided for the terms of use must reflect the most current version of the Health IT Developer’s terms of use. 	N/A

Note: This Certification Companion Guide (CCG) is an informative document designed to assist with health IT product development. The CCG is not a substitute for the 2015 Edition final regulation. It extracts key portions of the rule’s preamble and includes subsequent clarifying interpretations. To access the full context of regulatory intent please consult the 2015 Edition final rule or other included regulatory reference. The CCG is for public use and should not be sold or redistributed.

Version History

Version #	Change(s) Summary	Date Made
1.0	Initial Publication	Oct 30, 2015
1.1	Certification requirement revised to include that C-CDA creation performance (§ 170.315(g)(6) is required for this criterion. Clarifications added relating to “third-party API” definition, additional audit record user access details, data exclusions related to patient data accessed within a specific date range, terms of use details related to third party applications, API access, and hyperlink, and details around the meaning of token as a patient identifier.	Feb 5, 2016