

2015 Edition Certification Companion Guide

Social, Psychological, and Behavioral Data - 45 CFR 170.315(a)(15)

[Final Rule Preamble](#) – [Test Procedure](#)

Version 1.1 – Last Updated 12/08/2016

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	No	No	N/A

Certification Requirements

Privacy and Security: This certification criterion was adopted at § 170.315(a)(15). As a result, an ONC-ACB must ensure that a product presented for certification to a § 170.315(a) “paragraph (a)” 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 paragraph (a) 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.

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)) ○ Auditable events and tamper-resistance (§ 170.315(d)(2)) ○ Audit reports (§ 170.315(d)(3)) ○ Amendments (§ 170.315(d)(4)) ○ Automatic access time-out (§ 170.315(d)(5)) ○ Emergency access (§ 170.315(d)(6)) ○ End-user device encryption (§ 170.315(d)(7)) • 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))

Regulation Text

(15) Social, psychological, and behavioral data. Enable a user to record, change, and access the following patient social, psychological, and behavioral data:

(i) Financial resource strain. Enable financial resource strain to be recorded in accordance with the standard specified in § 170.207(p)(1) and whether a patient declines to specify financial resource strain.

(ii) Education. Enable education to be recorded in accordance with the standard specified in § 170.207(p)(2) and whether a patient declines to specify education.

(iii) Stress. Enable stress to be recorded in accordance with the standard specified in § 170.207(p)(3) and whether a patient declines to specify stress.

(iv) Depression. Enable depression to be recorded in accordance with the standard specified in § 170.207(p)(4) and whether a patient declines to specify depression.

(iv) Physical activity. Enable physical activity to be recorded in accordance with the standard specified in § 170.207(p)(5) and whether a patient declines to specify physical activity.

(v) Alcohol use. Enable alcohol use to be recorded in accordance with the standard specified in § 170.207(p)(6) and whether a patient declines to specify alcohol use.

(vi) Social connection and isolation. Enable social connection and isolation to be recorded in accordance the standard specified in § 170.207(p)(7) and whether a patient declines to specify social connection and isolation.

(vii) Exposure to violence (intimate partner violence). Enable exposure to violence (intimate partner violence) to be recorded in accordance with the standard specified in § 170.207(p)(8) and whether a patient declines to specify exposure to violence (intimate partner violence).

Criterion Subparagraph	Technical Explanations and Clarifications	Standard(s) Referenced
Applies to entire criterion	<p>Clarifications:</p> <ul style="list-style-type: none"> In order to certify to this criterion, health IT must be certified to all eight domains in (i)-(viii). These eight domains together provide a comprehensive picture of the patient that can facilitate care management and coordination. [see also 80 FR 62631] We provide the following OID to assist developers in the proper identification and exchange of health information coded to certain vocabulary standards. <ul style="list-style-type: none"> LOINC[®] OID: 2.16.840.1.113883.6.1 [see also 80 FR 62612] Health IT Modules can present for certification to a more recent version of LOINC[®] than version 2.52 per ONC's policy that permits certification to a more recent version of certain vocabulary standards. [see also 80 FR 62620] In addition to the privacy and security requirements for this criterion, we recommend that institutions develop and maintain policies for the collection and dissemination of the social, psychological, and behavioral data consistent with applicable federal and state laws. [see also 80 FR 62631] This criterion does not require that users capture this information, only that technology enables a user to capture this information with the required standards. 	<p>§ 170.207(c)(3) Logical Observation Identifiers Names and Codes (LOINC[®]) Database version 2.52</p> <p>§ 170.207(m)(1) The Unified Code of Units for Measure, Revision 1.9</p>

Criterion Subparagraph	Technical Outcome	Standard Referenced	LOINC [®] Code(s) for Question(s)	LOINC [®] Question Text	LOINC [®] Answer List ID	LOINC [®] Answer Text and ID								
(i)	A user can record, change, and access financial resource strain using the specified LOINC [®] codes and whether the patient declines to specify financial resource strain.	§ 170.207(p)(1)	76513-1	How hard is it for you to pay for the very basics like food, housing, medical care, and heating? [CARDIA]	LL3266-5	<table border="0"> <tr> <td>Very hard</td> <td>LA15832-1</td> </tr> <tr> <td>Hard</td> <td>LA14745-6</td> </tr> <tr> <td>Somewhat hard</td> <td>LA22683-9</td> </tr> <tr> <td>Not very hard</td> <td>LA22682-1</td> </tr> </table>	Very hard	LA15832-1	Hard	LA14745-6	Somewhat hard	LA22683-9	Not very hard	LA22682-1
Very hard	LA15832-1													
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Criterion Subparagraph	Technical Outcome	Standard Referenced	LOINC® Code(s) for Question(s)	LOINC® Question Text	LOINC® Answer List ID	LOINC® Answer Text and ID
(ii)	A user can record, change, and access education using the specified LOINC® codes and whether the patient declines to specify education.	§ 170.207(p)(2)	63504-5	What is the highest grade or level of school you have completed or the highest degree you have received? [NHANES]	LL1069-5	Never attended/kindergarten only – LA15606-9 1st grade – LA15607-7 2nd grade – LA15608-5 3rd grade – LA15609-3 4th grade – LA15610-1 5th grade – LA15611-9 6th grade – LA15612-7 7th grade – LA15613-5 8th grade – LA15614-3 9th grade – LA15615-0 10th grade – LA15616-8 11th grade – LA15617-6 12th grade, no diploma – LA15618-4 High school graduate – LA15564-0 GED or equivalent – LA15619-2 Some college, no degree – LA15620-0 Associate degree: occupational, technical, or vocational program – LA15621-8 Associate degree: academic program – LA15622-6 Bachelor’s degree (e.g., BA, AB, BS) – LA12460-4 Master’s degree (e.g., MA, MS, MEng, MEd, MSW, MBA) – LA12461-2 Professional school degree (example: MD, DDS, DVM, JD) – LA15625-9 Doctoral degree (example: PhD, EdD) – LA15626-7 Refused – LA4389-8 Don't know – LA12688-0

Criterion Subparagraph	Technical Outcome	Standard Referenced	LOINC® Code(s) for Question(s)	LOINC® Question Text	LOINC® Answer List ID	LOINC® Answer Text and ID
(iii)	A user can record, change, and access stress using the specified LOINC® codes and whether the patient declines to specify stress.	§ 170.207(p)(3)	76542-0	Do you feel stress - tense, restless, nervous, or anxious, or unable to sleep at night because your mind is troubled all the time - these days?	LL3267-3	Not at all – LA6568-5 Only a little – LA22687-0 To some extent – LA22686-2 Rather much – LA22685-4 Very much – LA13914-9
(iv)	A user can record, change, and access depression using the specified LOINC® codes and whether the patient declines to specify depression.	§ 170.207(p)(4)	55757-9	Patient Health Questionnaire 2 item (PHQ-2) [Reported]	N/A	N/A
			44250-9	(Q1) Little interest or pleasure in doing things?	LL358-3	Not at all – LA6568-5 Several days – LA6569-3 More than half the days – LA6570-1 Nearly every day – LA6571-9
			44255-8	(Q2) Feeling down, depressed, or hopeless?	LL358-3	Not at all – LA6568-5 Several days – LA6569-3 More than half the days – LA6570-1 Nearly every day – LA6571-9

Criterion Subparagraph	Technical Outcome	Standard Referenced	LOINC® Code(s) for Question(s)	LOINC® Question Text	LOINC® Answer List ID	LOINC® Answer Text and ID
(iv) continued	A user can record, change, and access depression using the specified LOINC® codes and whether the patient declines to specify depression.	§ 170.207(p)(4)	55758-7	Patient Health Questionnaire 2 item (PHQ-2) total score	With the answer coded with the associated applicable unit of measure using The Unified Code of Units for Measure, Revision 1.9	N/A
(v)	A user can record, change, and access physical activity using the specified LOINC® codes and whether the patient declines to specify physical activity.	§ 170.207(p)(5)	68515-6	How many days of moderate to strenuous exercise, like a brisk walk, did you do in the last 7D [SAMHSA]	With the answer coded with the associated applicable unit of measure using The Unified Code of Units for Measure, Revision 1.9	N/A

Criterion Subparagraph	Technical Outcome	Standard Referenced	LOINC® Code(s) for Question(s)	LOINC® Question Text	LOINC® Answer List ID	LOINC® Answer Text and ID
(v) continued	A user can record, change, and access physical activity using the specified LOINC® codes and whether the patient declines to specify physical activity.	§ 170.207(p)(5)	68516-4	On those days that you engage in moderate to strenuous exercise, how many minutes, on average, do you exercise? [SAMHSA]	With the answer coded with the associated applicable unit of measure using The Unified Code of Units for Measure, Revision 1.9	N/A
(vi)	A user can record, change, and access alcohol use using the specified LOINC® codes and whether the patient declines to specify alcohol use.	§ 170.207(p)(6)	72109-2	Alcohol Use Disorder Identification Test - Consumption [AUDIT-C]	N/A	N/A
			68518-0	How often do you have a drink containing alcohol?	LL2179-1	Never – LA6270-8 Monthly or less – LA18926-8 2-4 times a month –LA18927-6 2-3 times a week – LA18928-4 4 or more times a week – LA18929-2

Criterion Subparagraph	Technical Outcome	Standard Referenced	LOINC® Code(s) for Question(s)	LOINC® Question Text	LOINC® Answer List ID	LOINC® Answer Text and ID
(vi) continued	A user can record, change, and access alcohol use using the specified LOINC® codes and whether the patient declines to specify alcohol use.	§ 170.207(p)(6)	68519-8	How many standard drinks containing alcohol do you have on a typical day?	LL2180-9	1 or 2 LA15694-5 3 or 4 LA15695-2 5 or 6 LA18930-0 7 to 9 LA18931-8 10 or more LA18932-6
			68520-6	How often do you have 6 or more drinks on 1 occasion?	LL2181-7	Never LA6270-8 Less than monthly LA18933-4 Monthly LA18876-5 Weekly LA18891-4 Daily or almost daily LA18934-2
			75626-2	Total score [AUDIT-C]	N/A	N/A
(vii)	A user can record, change, and access social connection and isolation using the specified LOINC® codes and whether the patient declines to specify social connection and isolation.	§ 170.207(p)(7)	76506-5	Social connection and isolation panel	N/A	N/A

Criterion Subparagraph	Technical Outcome	Standard Referenced	LOINC® Code(s) for Question(s)	LOINC® Question Text	LOINC® Answer List ID	LOINC® Answer Text and ID
(vii) continued	A user can record, change, and access social connection and isolation using the specified LOINC® codes and whether the patient declines to specify social connection and isolation.	§ 170.207(p)(7)	63503-7	Are you now married, widowed, divorced, separated, never married or living with a partner?	LL1068-7	Married LA48-4 Widowed LA49-2 Divorced LA51-8 Separated LA4288-2 Never married LA47-6 Living with partner LA15605-1 Refused LA4389-8 Don't know LA12688-0
			76508-1	In a typical week, how many times do you talk on the telephone with family, friends, or neighbors [NHANES III]	With the answer coded with the associated applicable unit of measure using The Unified Code of Units for Measure, Revision 1.9	N/A

Criterion Subpara-graph	Technical Outcome	Standard Referenced	LOINC® Code(s) for Question(s)	LOINC® Question Text	LOINC® Answer List ID	LOINC® Answer Text and ID
(vii) continued	A user can record, change, and access social connection and isolation using the specified LOINC® codes and whether the patient declines to specify social connection and isolation.	§ 170.207(p)(7)	76509-9	How often do you get together with friends or relatives [NHANES III]	With the answer coded with the associated applicable unit of measure using The Unified Code of Units for Measure, Revision 1.9	N/A
			76510-7	How often do you attend church or religious services [NHANES]	With the answer coded with the associated applicable unit of measure using The Unified Code of Units for Measure, Revision 1.9	N/A

Criterion Subparagraph	Technical Outcome	Standard Referenced	LOINC® Code(s) for Question(s)	LOINC® Question Text	LOINC® Answer List ID	LOINC® Answer Text and ID
(vii) continued	A user can record, change, and access social connection and isolation using the specified LOINC® codes and whether the patient declines to specify social connection and isolation.	§ 170.207(p)(7)	76511-5	Do you belong to any clubs or organizations such as church groups unions, fraternal or athletic groups, or school groups [NHANES III]	LL963-0	Yes LA33-6 No LA32-8
			76512-3	Social isolation score [NHANES]	With the answer coded with the associated applicable unit of measure using The Unified Code of Units for Measure, Revision 1.9	

Criterion Subparagraph	Technical Outcome	Standard Referenced	LOINC® Code(s) for Question(s)	LOINC® Question Text	LOINC® Answer List ID	LOINC® Answer Text and ID
(viii)	A user can record, change, and access exposure to violence (intimate partner violence) using the specified LOINC® codes and whether the patient declines to specify exposure to violence (intimate partner violence).	§ 170.207(p)(8)	76499-3	Humiliation, Afraid, Rape, and Kick questionnaire [HARK]	N/A	N/A
			76500-8	Within the last year, have you been humiliated or emotionally abused in other ways by your partner or ex-partner [HARK]	LL963-0	Yes LA33-6 No LA32-8
			76501-6	Within the last year, have you been afraid of your partner or ex-partner [HARK]	LL963-0	Yes LA33-6 No LA32-8
			76502-4	Within the last year, have you been raped or forced to have any kind of sexual activity by your partner or ex-partner [HARK]	LL963-0	Yes LA33-6 No LA32-8
			76503-2	Within the last year, have you been kicked, hit, slapped, or otherwise physically hurt by your partner or ex-partner	LL963-0	Yes LA33-6 No LA32-8

Criterion Subparagraph	Technical Outcome	Standard Referenced	LOINC® Code(s) for Question(s)	LOINC® Question Text	LOINC® Answer List ID	LOINC® Answer Text and ID
(viii) continued	A user can record, change, and access exposure to violence (intimate partner violence) using the specified LOINC® codes and whether the patient declines to specify exposure to violence (intimate partner violence).	§ 170.207(p)(8)	76504-0	Total score [HARK]	With the answer coded with the associated applicable unit of measure using The Unified Code of Units for Measure, Revision 1.9	

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 27, 2015
1.1	Removed § 170.315(g)(3) reference from design and performance	Dec 08, 2016