

2015 Edition Certification Companion Guide

Computerized Provider Order Entry (CPOE) – Diagnostic Imaging - 45 CFR 170.315(a)(3)

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

Version 1.0 – Last Updated 10/22/2015

New/Revised/Unchanged Compared to 2014 Edition	Gap Certification Eligible	Base EHR Definition	Certified EHR Technology Definition	Associated EHR Incentive Program Objective(s)
Unchanged	Yes	Yes ¹	Included	Objective 4

Privacy and Security: This certification criterion was adopted at § 170.315(a)(3). 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.

- Safety-enhanced design (§ 170.315(g)(3)) must be explicitly demonstrated for this criterion.
- 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)) 	<ul style="list-style-type: none"> • Safety-enhanced design (§ 170.315(g)(3)) • Quality management system (§ 170.315(g)(4)) • Accessibility-centered design (§ 170.315(g)(5))

¹ To meet the 2015 Edition Base EHR definition, providers must possess technology that has been certified to at least one of the following: § 170.315(a)(1) CPOE – medications, § 170.315(a)(2) CPOE – laboratory, or § 170.315(a)(3) CPOE – diagnostic imaging.

Privacy and Security (§ 170.315(d))	Design and Performance (§ 170.315(g))
<ul style="list-style-type: none"> ○ 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. 	

Regulation Text

Computerized provider order entry – diagnostic imaging.

(i) Enable a user to record, change, and access diagnostic imaging orders.

(ii) Optional. Include a “reason for order” field.

Criterion Subparagraph	Technical Explanations and Clarifications	Standard(s) Referenced
(i)	<p>Technical outcome – The health IT permits a user to record, change, and access diagnostic imaging orders.</p> <p>Clarifications:</p> <ul style="list-style-type: none"> ● No standard is required for demonstrating the ability to allow a user to record, change, and access diagnostic imaging orders. ● This provision does not focus on the transmission of diagnostic imaging orders, only on the ability of a user to record, change, and access the diagnostic imaging order. [see also 77 FR 54248] 	N/A
(ii)	<ul style="list-style-type: none"> ● Technical outcome – The health IT allows for the user to include a “reason for order.” <p>Clarifications:</p> <ul style="list-style-type: none"> ● It is <u>not</u> mandatory that the health IT allow a user to include a “reason for order” field, however it is optional. The developer has the discretion to determine how to implement this optional provision (e.g., free text field or drop-down menu of pre-determined entries). 	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 22, 2015