§170.315(b)(3) Electronic prescribing

2015 Edition CCGs

Version 1.5 Updated on 02-24-2020

Revision History

Version #	Description of Change	Version Date
1.0	Initial Publication	10-29-2015
1.1	Added clarifications for paragraph (b)(3) (ii) regarding testing for medication/associated diagnosis/reason and oral liquid medication dosing.	01-26-2016
1.2	Added clarification for the entire criterion related to max field validation.	09-26-2016
1.3	Added clarification for the entire criterion regarding alerts for failed electronic prescriptions.	09-21-2018
1.4	Added clarification for certification program flexibility that allows upgrade to NCPDP SCRIPT standard version 2017071. Added clarification that ONC-ACBs will no longer offer certification to 170.315(b)(3) using the NCPDP 10.6 standard after 01/01/2020.	09-06-2019
1.5	Added additional clarification for	02-24-2020

	certification program flexibility that allows upgrade to NCPDP SCRIPT Standard Version 2017071. Added clarification on use of Inherited Certified Status (ICS) when submitting newer versions of Health IT Modules using version 2017071 of the standard.	

Regulation Text

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§170.315 (b)(3) *Electronic prescribing*—

(i) Enable a user to perform all of the following prescription-related electronic transactions in accordance with the standard specified in §170.205(b)(2) and, at a minimum, the version of the standard specified in §170.207(d)(3) as follows:
- (A) Create new prescriptions (NEWRX).
- (B) Change prescriptions (RXCHG, CHGRES).
- (C) Cancel prescriptions (CANRX, CANRES).
- (D) Refill prescriptions (REFREQ, REFRES).
- (E) Receive fill status notifications (RXFILL).
- (F) Request and receive medication history information (RXHREQ, RXHRES).

(ii) For each transaction listed in paragraph (b)(3)(i) of this section, the technology must be able to receive and transmit the reason for the prescription using the diagnosis elements in DRU Segment.

(iii) *Optional.* For each transaction listed in paragraph (b)(3)(i) of this section, the technology must be able to receive and transmit the reason for the prescription using the indication elements in the SIG Segment.

(iv) Limit a user's ability to prescribe all oral liquid medications in only metric standard units of mL (i.e., not cc).

(v) Always insert leading zeroes before the decimal point for amounts less than one and must not allow trailing zeroes after a decimal point when a user prescribes medications.

Standard(s) Referenced

Paragraph (b)(3)(i)

§ 170.205(b)(2) SCRIPT Standard, Implementation Guide, Version 10.6, October, 2008

§ 170.207(d)(3) RxNorm, September 8, 2015 Full Release Update

Certification Companion Guide: Electronic prescribing

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.

Link to Final Rule Preamble

Edition Comparision	Gap Certification Eligible	Base EHR Definition	In Scope for CEHRT Definition
Revised	No	Not Included	Yes

Certification Requirements

Privacy and Security: This certification criterion was adopted at § 170.315(b)(3). As a result, an ONC-ACB must ensure that a product presented for certification to a § 170.315(b) "paragraph (b)" 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 (b) 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.

Table for Privacy and Security

- If choosing Approach 1:
  - Authentication, access control, and authorization (§ 170.315(d)(1))
  - Auditable events and tamper-resistance (§ 170.315(d)(2))
  - Audit reports (§ 170.315(d)(3))
  - Automatic access time-out (§ 170.315(d)(5))
  - Emergency access (§ 170.315(d)(6))
  - End-user device encryption (§ 170.315(d)(7))
  - Integrity (§ 170.315(d)(8))
- If choosing Approach 2:
  - 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. Please see the 2015 Edition final rule correction notice at 80 FR 76870 for additional clarification.

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.

Table for Design and Performance

- Safety-enhanced design (§ 170.315(g)(3))
- Quality management system (§ 170.315(g)(4))
- Accessibility-centered design (§ 170.315(g)(5))

Technical Explanations and Clarifications

Applies to entire criterion

Clarifications:

- The intended scope of this certification criterion is the ability of health IT to electronically exchange information with external recipients. [see also FAQ #22]
- The criterion does not prohibit nor does it require controlled substances prescriptions to be supported in order to demonstrate compliance with its requirements. However, controlled substances could be used as part of testing and certification so long as the health IT has met DEA's requirements.
- With the exception of which test data elements might be required, this certification criterion applies equally to both inpatient and ambulatory settings.
- Max field length tests within certain portions of the SCRIPT 10.6 standard will not be in scope for the purposes of 2015 Edition testing. Errors received during testing related to the max field requirement can be treated as a warning. This does not remove the requirement from a surveillance perspective nor the general need for mandatory fields to be populated with data as required by the standard. Please consult NCPDP to engage in further dialogue regarding its standard's interpretive requirements.
- It is beyond the scope of this certification criterion to require the capability to ensure that a provider is actively alerted when an electronic prescription fails. [see also 77 FR 54200] Developers are advised, but not required, to include in its disclosures whether and how failed electronic prescriptions are presented to the end-user. Developers are also advised to incorporate how failed electronic prescriptions are presented to the end-user in its end-user training materials
- In response to the Centers for Medicare and Medicaid Services (CMS) requirement that electronic prescribing be conducted using solely the NCPDP SCRIPT Standard Version 2017071 starting January 1, 2020, developers of 2015 Edition Certified Health IT Modules certified to the e-prescribing criterion adopted at 45 CFR 170.315(b)(3) are permitted to update their products to use the NCPDP SCRIPT Standard Version 2017071 to meet CMS' compliance requirements and will not invalidate or place at risk the product(s) certification to 170.315(b)(3).
- Based on the CMS requirement above, effective 1/1/2020 the ONC Health IT Certification Program will not permit ONC-ACBs to grant Health IT Modules certification to the 170.315(b)(3) criterion which includes the NCPDP 10.6 standard.
- As of January 1, 2020, developers that have Health IT Modules certified to the 170.315(b)(3) criterion and have updated their products to use the NCPDP SCRIPT Standard Version 2017071 to meet CMS' compliance requirements may request of the ONC-ACB Inherited Certified Status (ICS) flexibility for a Health IT Module. Developers must inform their ONC-ACB of the updates and request to maintain

certification to 170.315(b)(3) by applying for ICS. For more information about ICS, please refer to: https://www.healthit.gov/faq/b12-how-does-inherited-certification-status-work-ehr-modules).

Paragraph (b)(3)(i)

Technical outcome – A user can send and receive the specified prescription transactions electronically per the NCPDP SCRIPT Standard Implementation Guide Version 10.6 and using RxNorm vocabulary codes.

Clarifications:

- Health IT Modules can present for certification to a more recent version of RxNorm than the September 8, 2015 Release per ONC's policy that permits certification to a more recent version of certain vocabulary standards. [see also 80 FR 62620]
- We provide the following OID to assist developers in the proper identification and exchange of health information coded to certain vocabulary standards.
  - RxNorm OID: 2.16.840.1.113883.6.88. [see also 80 FR 62612]
- We intend for the RxNorm concept unique identifiers (RXCUIs) to be used as drug qualifiers. [see also 77 FR 54199]
- All medications may not yet have an equivalent RxNorm code. Where no RxNorm code exists, nothing prohibits another allowable code from being used. However, where corresponding RxNorm codes exist, health IT must be able to use those codes. [see also 77 FR 54199]
- There are other standards and services available for requesting and receiving medication history information. Health IT must be certified to request and receive medication history information per the NCPDP SCRIPT IG Version 10.6, but that does not preclude developers from incorporating and using technology standards or services not required by our regulation. [see also 80 FR 62641]
- Developers have flexibility in determining how message notifications are presented to users. We recommend developers and providers work together to determine whether batch-notification is preferable to real-time messaging alerts. Note that the notifications will differ based on the message type. [see also 80 FR 62642]

Paragraphs (b)(3)(ii) and (iii) *Optional*

Technical outcome – For all transactions in provision (b)(3)(i), health IT can send and receive the medication-associated diagnosis/reason for prescription using the diagnosis elements in the DRU Segment.

- Optional – For all transactions in provision (b)(3)(i), health IT can send and receive the indication/reason for prescription using the indication elements in the SIG segment.

Clarifications:

- For all health IT certified to this criterion, the health IT must be able to send and receive medication-associated diagnosis/reason for prescription using the diagnosis elements in the DRU Segment. NCPDP SCRIPT Version 10.6 supports this method using ICD-9-CM codes or ICD-10-CM codes with an additional qualifier. [see also 80 FR 62643]
- We intend to test compliance with ICD-10 for the medication-associated diagnosis/reason for prescription using the diagnosis elements in the DRU Segment. [see also 80 FR 62643]
- Note that testing will not test that the health IT can send and receive the medication/associated diagnosis/reason for prescription for the CANRES and RXHREQ messages because the NCPDP SCRIPT v10.6 standard does not include the DRU segment in these messages.
- If the developer chooses, the health IT can also be certified to send and receive the indication/reason for prescription using the indication elements in the SIG segment. This would require that the developer has voluntarily chosen to implement Structured and Codified Sig Format v1.2.[1] NCPDP

SCRIPT Version 10.6 supports this method using SNOMED CT® codes. [see also 80 FR 62643] Note that NCPDP has also provided guidance on implementing Structured and Codified Sig in the NCPDP SCRIPT Implementation Recommendations starting with Version 1.29.[2]

[1] NCPDP's Structured and Codified Sig Format Implementation Guide v1.2 is within the NCPDP SCRIPT v10.6 standard. Please see: https://www.ncpdp.org/NCPDP/media/pdf/StandardsMatrix.pdf.

[2] http://www.ncpdp.org/Resources/ePrescribing

Paragraph (b)(3)(iv)

Technical outcome – Oral liquid medications can only be electronically prescribed using "mL" units.

Clarifications:

- We clarify that the volume for oral liquid medications must be prescribed using "mL" units. Testing and certification do not address the concentration of active ingredients, which is the amount of active ingredient per unit of volumetric measure (e.g., 5 mg per ml). When needed, developers should represent concentrations of active ingredients using the appropriate units of measurement.
- E-prescribing of oral liquid medications using "cc" units will not be permitted for certification. [see also 80 FR 62643]
- While not required for certification, we also encourage developers to implement "tall man lettering" to differentiate between drug names that are similar and commonly confused.[3] [see also 80 FR 62643]

[3] http://www.ismp.org/Tools/tallmanletters.pdf

Paragraph (b)(3)(v)

Technical outcome – For all e-prescribed medications, the health IT always inserts leading zeroes before the decimal point for amounts less than one and never allows trailing zeroes after a decimal point.

Clarifications:

- No additional clarifications available.

Content last reviewed on November 4, 2020