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ALERT - Health Care

Summary of Compliance Dates in the ONC Cures Act COVID-19 Interim Final Rule with Comment Period

On October 29, 2020, the United States Department of Health and Human Services Office of the National Coordinator for Health Information Technology ("ONC") released an <u>interim final rule with comment period</u> ("IFC") that delays compliance dates for information blocking and other health information technology ("IT") requirements under the 21st Century Cures Act ("Cures Act") due to the COVID-19 Public Health Emergency. ONC had implemented these requirements in a final rule issued on May 1, 2020 ("ONC Cures Act Final Rule"). The IFC includes the following tables to summarize the new compliance dates for information blocking and other requirements introduced in the ONC Cures Act Final Rule:

Conditions and Maintenance of Certification Requirements Applicability and Compliance Dates (Table 1 in the IFC)

Provision	Final Rule	Enforcement Discretion Announcement	Interim Final Rule with Comment Period
Information Blocking Overall Applicability Date – (45 CFR part 171) ²	November 2, 2020	N/A – No Change	
Condition of Certification (CoC) – Information Blocking – (§ 170.401)	November 2, 2020	3 months after the compliance timeframe	
CoC – Assurances – (§ 170.402(a)(1)) –Will not take any action that constitutes information blocking or actions that inhibit access, exchange, and use of electronic health information (EHI)	November 2, 2020	3 months after the compliance timeframe	Appl 5 2021
CoC – Assurances – (§ 170.402(a)(2) and (3), and (b)(1)) – Other	Effective date: June 30, 2020	Enforcement discretion expired 3 months after the effective date of the final rule	April 5, 2021
CoC – Communications – (§ 170.403) – Communications requirements, except for § 170.403(b)(1) where we removed the notice requirement for 2020	Effective date: June 30, 2020	Enforcement discretion expired 3 months after the effective date of the final rule	
CoC – API – (§ 170.404(b)(4)) – Compliance for current API criteria	November 2, 2020	3 months after the compliance timeframe	

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¹ See 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Final Rule, 85 Fed. Reg. 25,642 (May 1, 2020).

² Note that for the Content and Manner Exception, in § 171.301(a), for the period before October 6, 2022, the definition of EHI is limited to, at a minimum, the data elements represented in the USCDI standard; and, for the period on and after Oct 6, 2022, EHI is defined as it is in § 171.102. These dates reflect the extension from May 2, 2022, which was the compliance date included in the ONC Cures Act Final Rule. These dates are discussed in more detail in section II.A.1 [of the IFC].

ROPES&GRAY

ALERT - Page 2

Provision	Final Rule	Enforcement Discretion Announcement	Interim Final Rule with Comment Period	
CoC – API – (§ 170.404(b)(3)) –Rollout of new standardized API functionality	May 2, 2022	3 months after the compliance timeframe	December 31, 2022	
CoC – Real World Testing – 2015 Edition health IT certification criteria with standards updates	May 2, 2022	3 months after the compliance timeframe	December 31, 2022	
CoC – Assurances – (§ 170.402(a)(4) and (b)(2)) -EHI Export Rollout	May 1, 2023	3 months after the compliance timeframe	December 31, 2023	
CoC – Communications – (§ 170.403(b)(1)) – Notice to all customers with which developer has contracts or agreements containing provisions that contravene Communications CoC	Annually beginning in calendar year 2020	Notice can be made until March 31, 2021, for the 2020 calendar year	Begin annual cycle 1 year later CY 2021	
CoC – Initial Attestations – (§ 170.406)	April 1-30, 2021 attestation window for attestation period running June 30, 2020, through March 31, 2021	Generally remains the same except for the initial attestation, which will now be accepted through July 30, 2021	Begin annual cycle 1 year later CY 2022	
CoC – Real World Testing – (§ 170.405(b)(1) and (2)) Submit <i>initial</i> plan and <i>initial</i> results submission	Plan: December 15, 2020 Results: March 15, 2022	Initial Plan: Initial RWT plans (i.e., 2021 RWT plans) may be submitted through March 15, 2021 Initial Results: Initial RWT results from the 2021 performance year may be submitted up through June 2022	Begin annual cycle 1 year later Initial Plan: December 15, 2021 Initial Results: March 15, 2023	

2015 Edition Certification Criteria Cures Update (Table 2 in the IFC)

Certification Criteria	Reference	2015 Edition Cures Update – Timing	Impact on CMS Promoting Interoperability (PI) Programs
Transitions of Care	§ 170.315(b)(1)	Update to adopted USCDI/C-CDA companion guide by December 31, 2022	PI Measures: Support Electronic Referral Loops by Sending Health Information Support Electronic Referral Loops by Receiving and Incorporating Health Information
Clinical information reconciliation and incorporation	§ 170.315(b)(2)	Update to adopted USCDI/C-CDA companion guide by December 31, 2022	PI Measures: • Support Electronic Referral Loops by Receiving and Incorporating Health Information

ROPES&GRAY

ALERT • Page 3

Certification Criteria	Reference	2015 Edition Cures Update – Timing	Impact on CMS Promoting Interoperability (PI) Programs
Electronic prescribing § 170.315(b)(§ 170.315(b)(3)	Update to adopted NCPDP SCRIPT standard version 2017071 by December 31, 2022	PI Measures:
			• e-Prescribing
			• Query of PDMP
Data Export	§ 170.315(b)(6)	ONC-ACBs may only issue certificates for this criterion for the period before December 31, 2023	Removed from 2015 Edition Base EHR definition effective date of the final rule (60 days after publication)
Security tags -summary of care – send	§ 170.315(b)(7)	Document, section, and entry (data element) level; or Document level for the period before December 31, 2022	
Security tags -summary of care – receive	§ 170.315(b)(8)	Document, section, and entry (data element) level; or	
		Document level for the period before December 31, 2022	
Care plan	§ 170.315(b)(9)	Update to C-CDA companion guide referenced in § 170.205(a)(4) and § 170.205(a)(5) by December 31, 2022	
EHI export	§ 170.315(b)(10)	Certify to new criterion by December 31, 2023	
Clinical quality measures (CQMs) – report	§ 170.315(c)(3)	Update to CMS QRDA Category I/IIIIG by December 31, 2022	PI Programs
Auditable events and tamper-resistance	§ 170.315(d)(2)	Update to ASTM 2147-18 standard by December 31, 2022	
Audit report(s)	§ 170.315(d)(3)	Update to ASTM 2147-18 standard by December 31, 2022	
Auditing actions on health information	§ 170.315(d)(10)	Update to ASTM 2147-18 standard by December 31, 2022	
View, Download, and Transmit to 3rd Party	§ 170.315(e)(1)	Update to USCDI referenced in § 170.213 and C-CDA companion guide referenced in § 170.205(a)(4) and § 170.205(a)(5) by December 31, 2022	PI Measure: Provide Patients Electronic Access to Their Health Information
Transmission to public health agencies – electronic case reporting	§ 170.315(f)(5)	Update to USCDI referenced in § 170.213 by December 31, 2022	PI Measure: Electronic Case Reporting
Consolidated CDA creation performance	§ 170.315(g)(6)	Update to USCDI referenced in § 170.213 and C-CDA companion guide referenced in § 170.205(a)(4) and § 170.205(a)(5) by December 31, 2022	
Application Access – Data Category Request	§ 170.315(g)(8)	ONC-ACBs may only issue certificates for this criterion for the period before December 31, 2022	PI Measure: Provide Patients Electronic Access to Their Health Information

ROPES & GRAY

ALERT • Page 4

Certification Criteria	Reference	2015 Edition Cures Update – Timing	Impact on CMS Promoting Interoperability (PI) Programs
Application Access – All Data Request	§ 170.315(g)(9)	Update to USCDI referenced in § 170.213 and C-CDA companion guide referenced in § 170.205(a)(4) and § 170.205(a)(5) by December 31, 2022	PI Measure: Provide Patients Electronic Access to Their Health Information
Standardized API for patient and population services	§ 170.315(g)(10)	Certify to new criterion by December 31, 2022	Added to the 2015 Edition Base EHR definition PI Measure: Provide Patients Electronic Access to Their Health Information