ORIGINAL KEY COMPLIANCE REQUIREMENTS AND DEADLINES FOR ONC AND CMS RULES REGARDING INTEROPERABILITY, INFORMATION BLOCKING, PATIENT ACCESS, AND HEALTH IT CERTIFICATION

UPDATED 4/28/2020 WITH INFORMATION ON PUBLICATION DATES, IMPLEMENTATION DEADLINES, AND ENFORCEMENT DELAYS

ADDITIONAL UPDATES FROM 10/29/2020 INTERIM FINAL RULE WITH COMMENT ANNOUNCEMENT

ONC FINAL RULE **PLANNED PUBLICATION DATE – MAY 1, 2020** Final Rule: 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program		
Regulatory Requirement Description	**Relevant Regulatory Section(s) and Description**	**Compliance or Enforcement Deadline**
General Effective Date of Rules	Applies to removal of pre-2015 Edition certification criteria from: • 45 C.F.R. § 170.315(a)(6) (problem list) • 45 C.F.R. § 170.315 (a)(7) (medication list) • 45 C.F.R. § 170.315 (a)(8) (medication allergy list) • 45 C.F.R. § 170.315 (a)(11) (smoking status) • 45 C.F.R. § 170.315 (b)(4)(CCDS –Create) • 45 C.F.R. § 170.315 (b)(5)(CCDS –Receive) and revisions of the following: ▪ 45 C.F.R. § 170.315(b)(3) ePrescribing ▪ 45 C.F.R. § 170.315(b)(7) Security Tags – Summary of Care (send) (formerly, DS4P – Send) ▪ 45 C.F.R. § 170.315(b)(8) Security Tags – Summary of Care (receive) (formerly, DS4P – Receive) ▪ 45 C.F.R. § 170.315(c)(3) CQMs – Report ▪ 45 C.F.R. § 170.315(d)(2) Adjustable Events and Tamper-Resistance ▪ 45 C.F.R. § 170.315(d)(3) Audit Report(s) ▪ 45 C.F.R. § 170.315(d)(10) Auditing Actions on Health Information	60 days after publication date (July 1, 2020). For removed criteria, certified health IT products will no longer need to certify to including these elements. Any certification of health IT submitted or subject to maintenance of certification 60 days after publication date (July 1, 2020) will need to comply with revised criteria definitions. New and Revised Certification Criteria for implementation of § 170.315 (b)(3), (b)(7), (b)(8), (c)(3), (d)(2), (d)(3), (d)(10), (d)(12), and (d)(13) begins **December 31, 2022.**
Phase out of ONC-ACB certification issuances	• 45 C.F.R. § 170.315(a)(10)(drug/formulary preferred drug list checks), • 45 C.F.R. § 170.315 (a)(13) (patient-specific education resource), • 45 C.F.R. § 170.315 (b)(6) (data export), and	Ends January 1, 2022 with sunset of Medicare Promoting Interoperability Program (except for § 170.315(b)(6), which ends 36 months

	• 45 C.F.R. § 170.315 (e)(2) (secure messaging)	after publication date (May 2, 2023)).
Information Blocking Definitions and Exceptions	45 C.F.R. part 171 (definitions and exceptions)	6 months after publication date (compliance beginning **April 5, 2021** enforcement discretion dependent on OIG's Final Rule on civil monetary penalties)
Conditions and Maintenance of Certification (CoC) Requirements - Information Blocking	45 C.F.R. § 170.401 (information blocking condition of certification requirement) Prohibits any "health IT developer" who has at least one health IT product certified under the Program from taking any action that constitutes information blocking as defined by section 3022(a) of the Public Health Service Act and proposed in 45 C.F.R. § 171.103.	6 months after publication date (compliance beginning **April 5, 2021**, but enforcement discretion for 3 more months (February 2, 2021)).
Minimum USCDI Data Elements Required for Compliance with 2015 Edition Cures Update Certification Criteria	• 45 C.F.R. § 170.102 • 45 C.F.R. § 170.213 (U.S. Core Data for Interoperability (USCDI) standard) • 45 C.F.R. § 170.315(g)(10) (new Standardized API for Patient and Population Services certification criterion referencing USCDI - replaces old 45 C.F.R. § 170.315(g)(8)) • 45 C.F.R. § 170.405(b)(3)(details required application of USCDI updates for Consolidated-Clinical Document Architecture (C-CDA)) ONC Final Rule adopts conforming changes to the following provisions to update Common Clinical Data Set-criteria associated with 2015 Health Certification for consistency with USCDI standard, which will be required for all certified health IT products after the compliance date: • 45 C.F.R. § 170.315(b)(1) Transitions of Care	Health IT developers must update certified health IT to comply with changes no later than 24 months after publication date (until **December 31, 2022**)

	• 45 C.F.R. § 170.315(b)(2) Clinical Information Reconciliation and Incorporation (revised to replace "medication allergies" data element with "Allergies and Intolerances" data class) • 45 C.F.R. § 170.315(e)(1) View, Download, and Transmit to a 3rd Party • 45 C.F.R. § 170.315(f)(5) Transmission to Public Health Agencies – Electronic Case Reporting • 45 C.F.R. § 170.315(g)(6) Consolidated CDA Creation Performance • 45 C.F.R. § 170.315(g)(9) Application Access – All Data Request	
Minimum USCDI Data Elements Required for Compliance with Information Blocking Prohibition	45 C.F.R. § 171.103(b) Note: Actors that receive requests for EHI are not required to use certified health IT to fulfill such requests, but must provide USCDI-compliant data elements.	Months 6-24 after publication date (until **October 6, 2022**).
Full "Electronic Health Information" (EHI) Definition in Effect for Information Blocking Compliance Purposes	45 C.F.R. § 171.103(b)	24 months after publication date (compliance beginning **October 6, 2022**).
HL7 FHIR API Capability Rollout	45 C.F.R. § 170.215 (standard) and 45 C.F.R. § 170.315(g)(10) (use)	No later than 24 months after publication date (**December 31, 2022**).
EHI Export Capability Rollout	45 C.F.R. § 170.315(b)(10)	No later than 36 months after publication date (**December 31, 2023**).
Attestations for CoC	45 C.F.R. § 170.406 (attestations for certified Health IT CMCs) Health IT developers will be able to submit their attestations within a	First 30-day attestation submission window begins April 1, 2021 (extended to **April 1-30, 2022**), for attestation periods between the

	designated 30-day window twice a year for purposes of compliance.	effective date of the final rule and March 31, 2021. Subsequent semiannual submissions during 30-day windows (e.g., October 1, 2021-October 31, 2021 - window for attestation period of April 1 through September 30, 2021).
CoC Requirements Related to Information Blocking Assurances:	45 C.F.R. § 170.402 45 C.F.R. § 170.315 Requires that a health IT developer, as a Condition and Maintenance of Certification requirement under the ONC Health IT Certification Program ("Program"), provide assurances to the Secretary, unless for legitimate purposes specified by the Secretary, that it will not take any action that constitutes information blocking as defined in section 3022(a) of the PHSA, or any other action that may inhibit the appropriate exchange, access, and use of electronic health information (EHI).	6 months after publication date (compliance beginning **April 5, 2021**). Note that compliance date for 42 C.F.R. § 170.402(a)(4) and (b)(2) is **December 31, 2023** as it relates to § 170.315(b)(10) – EHI Export Rollout).
CoC Requirements Related to Protected Communications	45 C.F.R. § 170.403 Prohibits health IT developers from restricting "protected communications" regarding the following subjects: usability of the health information technology; interoperability of the health information technology; security of the health information technology; relevant information regarding users' experiences when using the health information technology; business practices of developers of health information technology related to exchanging electronic health information; and manner in which a user of the health information technology has used such technology. Certain narrow exceptions to the above are set out	Effective date of final rule (**April 5, 2021**). **No notice requirement for 2020 under 42 C.F.R. § 170(b)(1).**

	in the regulation.	
CoC Requirements Related to APIs	• 45 C.F.R. § 170.404(API technology supplier, API data provider, and API user definitions, among others) • 45 C.F.R. § 170.213 (USCDI definition) • 45 C.F.R. § 170.215 (API standards - FHIR and USCDI provisions) • 45 C.F.R. § 170.315(g)(10) (standardized API for Patient and Population Services (new certification criterion that also refers to the USCDI) Requires health IT developers to publish APIs that allow "health information from such technology to be accessed, exchanged, and used without special effort through the use of APIs or successor technology or standards, as provided for under applicable law."	6 months after publication date (compliance by Certified API Developers with current API criteria beginning **April 5, 2021**; compliance with new standardized API functionalities beginning **December 31, 2022**).
First Real-World Testing Plans Due	45 C.F.R. § 170.405 Health IT developers must successfully test the real world use of the technology for interoperability in the type of setting in which such technology would be marketed. **NOTE:** CMS finalized that document-level tagging remains applicable for up to 24 months after the publication date of the final rule. For certification and compliance of Health IT Modules certified after 24 months after the publication date of this final rule, only the full scope of the HL7 Data Segmentation for Privacy (DS4P) standard is applicable. HL7 DS4P standard provides a means to express obligations and disclosure restrictions that may exist for sensitive data.	Dec. 15, 2020 (deadline for publishing the plan via publicly accessible hyperlink on the Certified Health IT Products List (plan deadline extended to **December 15, 2021**, and initial Real World Testing Results may be submitted until **March 15, 2023**).
Information Blocking Civil Monetary Penalties (enforced by the HHS Office of the Inspector	**Proposed Rule published in Federal Register on April 24, 2020.** **NOTES:** This does not foreclose the possibility that the OIG will still rely on its statutory authority to accept complaints regarding information blocking	**Solicitation for Comments on Effective Date:** OIG seeks comments (due June 23, 2020) on these proposed approaches for the effective

General (OIG)) Alert Available Here	allegations, investigate such claims, and/or engage in other monitoring or audit activities with respect to information blocking independently or in coordination with ONC, or from pursuing enforcement against actors for false attestations submitted to the ONC related to health IT certification criteria in coordination with the Department of Justice under the False Claims Act. **OIG's CMP authority only applies to HIEs/HINs and health IT developers; it does not extend to health care providers**. If OIG determines that a health care provider has committed information blocking, "it shall refer such health care provider to the appropriate agency for appropriate disincentives," which will be established by the Secretary in future notice and comment rulemaking.	date of OIG's information blocking CMP regulations: Option 1: 60 days after OIG CMP rule becomes FINAL. Option 2: October 1, 2020.

CMS PATIENT ACCESS RULE **PLANNED PUBLICATION DATE – MAY 1, 2020** CMS Finalizes New Requirements on Health Plans to Release Health Data; Updates Medicare Conditions of Participation for Hospitals to Send Electronic Notifications		
Regulatory Requirement Description	**Relevant Regulatory Section(s) and Description**	**Compliance or Enforcement Deadline**
Digital Contact Information to be reported on NPPES	Cures Act section 4003 Requires the HHS Secretary to create a provider digital contact information index that includes all individual health care providers and facilities. CMS plans to update the National Plan and Provider Enumeration System (NPPES) to include data fields to collect, for example, Direct Addresses, FHIR server URLs, query endpoints and/or other "electronic service information." CMS will publicly report the names and NPIs of those providers who	Second half of 2020 CMS information collection request under the Paperwork Reduction Act of 1995 will be published for review and comment.

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	do not have digital contact information that can be used to facilitate the secure sharing of health information. CMS has not yet identified where this reporting will be publicized.	
Admission, Discharge and Transfer Event Notifications	Hospitals - 42 C.F.R. § 482.24(d), Psychiatric Hospitals - 42 C.F.R. § 482.61(f), Critical Access Hospitals (CAHs) - 42 C.F.R. § 485.638(d). Revises the Conditions of Participation for Medicare- and Medicaid-participating hospitals, psychiatric hospitals, and CAHs by adding a new standard, "Electronic Notifications," that will require hospitals, psychiatric hospitals, and CAHs to make electronic patient event notifications available to applicable post-acute care services providers and suppliers, and to community practitioners such as the patient's established primary care practitioner, established primary care practice group or entity, or other practitioner or practice group or entity identified by the patient as primarily responsible for his or her care. This requirement is limited to only those hospitals, psychiatric hospitals, and CAHs that utilize electronic medical records systems, or other electronic administrative systems, which are conformant with the content exchange standard at 45 C.F.R. § 170.205(d)(2).	**Enforcement Begins: May 1, 2021.** The new Conditions of Participation at 42 C.F.R. Parts 482 and 485 will now be effective 12 months after the final rule is published in the Federal Register.

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Patient Access API	▪ 42 C.F.R. § 422.119 (Medicare Advantage (MA) organizations) ▪ 42 C.F.R. § 431.60 (Medicaid Fee-for-Service (FFS)) ▪ 42 C.F.R. § 438.242 (Medicaid Managed Care) ▪ 42 C.F.R. § 457.730 (Children's Health Insurance Program (CHIP) FFS) ▪ 42 C.F.R. § 457.123 (CHIP Managed Care) ▪ 45 C.F.R. § 156.221 (QHP issues on Federally Facilitated Exchanges)	**Enforcement Begins: July 1, 2021 (including for QHPs).** CMS will exercise enforcement discretion for new requirements under 45 CFR Part 156 (QHPs) 42 CFR Parts 422, 431, 438, and 457 (other CMS-regulated payers) for six months, as a result of COVID-19. Requirements effective: January 1, 2021
Provider Directory API	▪ 42 C.F.R. 422.120 for (MA organizations) ▪ 42 C.F.R. 431.70 (Medicaid state agencies) ▪ 42 C.F.R. 438.242(b)(6) (Medicaid managed care plans) ▪ 42 C.F.R. 457.760 (CHIP state agencies) ▪ 42 C.F.R. 457.1233(d)(3) (CHIP managed care entities)	**Enforcement Deadline: July 1, 2021.** CMS will exercise enforcement discretion for new requirements under 42 CFR Parts 422, 431, 438, and 457 for six months, as a result of COVID-19. Requirements effective: January 1, 2021
Payer-to-Payer Data Exchange	▪ 42 C.F.R. 422.119(f) (MA organizations) ▪ 42 C.F.R. 438.62(b)(1)(vi) (Medicaid managed care plans) ▪ 42 C.F.R. § 457.1216 (CHIP managed care entities),	January 1, 2022 CMS-regulated payers are required to exchange patient clinical data at the patient's

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	▪ 45 C.F.R. 156.221(f) (Qualified Health Plan (QHP) issuers on the Federally Facilitated Exchanges) ▪ 45 C.F.R. § 170.213 (exchange content standard – currently USCDI version 1)	request, as patients move between CMS-regulated payers for services dated on or after January 1, 2016.
Frequency of Federal-State Data Exchanges for Dual-Eligible Patients	42 C.F.R. §§ 406.26 and 407.40 Requires all states to participate in daily exchange of buy-in data with CMS, with "daily" meaning every business day, but that if no new transactions are available to transmit, data would not need to be submitted on a given business day	April 1, 2022
Physician Compare Reporting	Indicator that eligible clinicians and groups submitted "no" responses to any of the three prevention of information blocking statements for Merit-based Incentive Payment System (MIPS)	Starting with the 2019 performance period data available for public reporting starting in late 2020.
Public Website Reporting	List of eligible hospitals or CAHs attesting under the Medicare FFS Promoting Interoperability Program that submitted a "no" response to any of the three attestation statements related to the prevention of information blocking.	Starting with the 2019 performance period data available for public reporting starting in late 2020.