Information Blocking and the ONC Health IT Certification Program: Extension of Compliance Dates and Timeframes in Response to the COVID-19 Public Health Emergency Interim Final Rule

Overview

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Please Note:

- The materials contained in this presentation are based on the provisions contained in 45 C.F.R. Parts 170 and 171. While every effort has been made to ensure the accuracy of this restatement of those provisions, this presentation is not a legal document. The official program requirements are contained in the relevant laws and regulations. Please note that other Federal, state and local laws may also apply.

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Purpose of the ONC Cures Act Final Rule

The ONC Cures Act Final Rule fosters innovation in health care to deliver better information, more conveniently, to patients and their providers. It also promotes transparency through technology, providing opportunities for the American public to gain visibility into the services, quality, and costs of health care.

- ✓ **Patients**: Right of Access to their Chart, Supporting Patient Privacy and Security, the Ability to Shop for Care and Avoid Bankruptcy

- ✓ **Doctors and Hospitals**: Making Patient's Chart Data Requests Easy and Inexpensive, Allowing Choice of Software, Implementation

- ✓ **Patients, Doctors, and Hospitals**: Improving Patient Safety

- ✓ **Health IT Developers**: Minimizing API Development and Maintenance Costs, Protecting Intellectual Property

- ✓ **American Public**: Maximizing Innovation, Transparency in Health Care

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Enforcement Discretion

- In the ONC Cures Act Final Rule, we set compliance dates and timeframes to meet certain requirements related to the information blocking provisions and Conditions and Maintenance of Certification requirements.

- On April 21, 2020, we first responded to health IT stakeholders' concerns about the COVID-19 pandemic by exercising enforcement discretion and providing three months after each initial date or timeline for all new requirements under the ONC Health IT Certification Program.

For More Information
https://www.healthit.gov/curesrule/resources/enforcement-discretion-archived

Announcement – ONC Interim Final Rule

On October 29, 2020, ONC announced an interim final rule in which ONC is extending compliance dates and timeframes for information blocking and the ONC Health IT Certification Program due to the COVID-19 Pandemic.

The interim final rule will be effective 30 days after publication in the Federal Register except for the information blocking provisions and related Conditions of Certification requirements which **are effective immediately** upon publication.

- Extending the applicability date for the Information Blocking provisions.

- Extending the compliance dates in the ONC Health IT Certification Program (Program), including certain 2015 Edition health IT certification criteria and Conditions and Maintenance of Certification requirements.

- Making changes to the Program by updating standards and clarifying regulatory text for specific certification criteria.

- Making technical corrections and clarifications.

Information Blocking

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Compliance Date Extensions

Who?

Those subject to the information blocking regulation include:

- Health Care Providers
- Health IT Developers of Certified Health IT
- HINs/HIEs

What?

- Applicability of information blocking provisions

- Dates for which EHI is limited to the data elements represented in the USCDI in the Information Blocking definition and the Content and Manner Exception

When?

➡ April 5, 2021

➡ October 6, 2022

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Who are the "actors" covered by information blocking?

**Health Care
Providers**
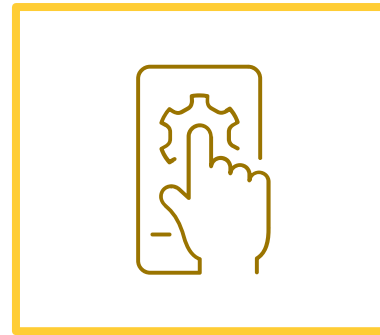
**Health IT
Developers of
Certified Health IT**
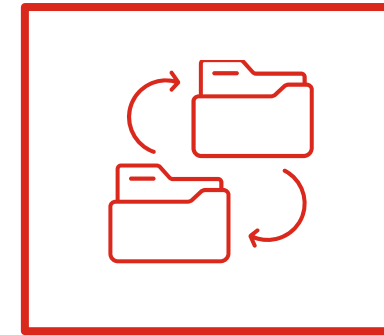
**Health Information
Networks (HIN)/
Health Information
Exchanges (HIE)**

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Applicability Date Extension

The interim final rule moves the applicability date from **November 2, 2020 to April 5, 2021.**

This means that actors now will be subject to the information blocking provisions beginning on **April 5, 2021**.

Information Blocking Definition and Content and Manner Exception

- Because we extended the applicability date for information blocking, we also revised the information blocking definition to extend the period of time for which the EHI is limited to the data elements represented in the USCDI to the period before **October 6, 2022**.

- Likewise, in the Content and Manner Exception, to be consistent with our original intent to narrow the scope of the EHI definition to just the data elements represented in the USCDI for the first 18 months after the applicability date, we revised the following dates:

  1. **For the period before October 6, 2022**, an actor must respond to a request to access, exchange, or use EHI with, *at a minimum*, the EHI identified by the **data elements represented in the USCDI standard**.

  2. **On and after October 6, 2022,** an actor must respond to a request to access, exchange, or use EHI with **EHI as defined in § 171.102**.

Investigations and Penalties/ Disincentives

Actors that are subject to the information blocking regulations may be investigated by the HHS Office of Inspector General if they are the subject of a claim of information blocking.

Actors found to have committed information blocking are subject to penalties:

- Health IT developers of certified health IT, health information networks, and health information exchanges → Civil monetary penalties (CMPs) up to $1 million per violation

- Health care providers → Appropriate disincentives to be established by the Secretary

New Applicability Dates included in ONC Interim Final Rule

Information Blocking and the ONC Health IT Certification Program:
Extension of Compliance Dates and Timeframes in Response to the COVID-19 Public Health Emergency Interim Final Rule

Information Blocking

4/5/2021
Applicability Date for Information Blocking Provisions

2020 — 2021 — 2022 — 2023

4/5/2021 through 10/5/2022
EHI definition is limited to the EHI identified by the data elements represented in the USCDI

On and after 10/6/2022
EHI definition is no longer limited to the EHI identified by the data elements represented in the USCDI

EHI = Electronic Health Information   USCDI = United States Core Data for Interoperability
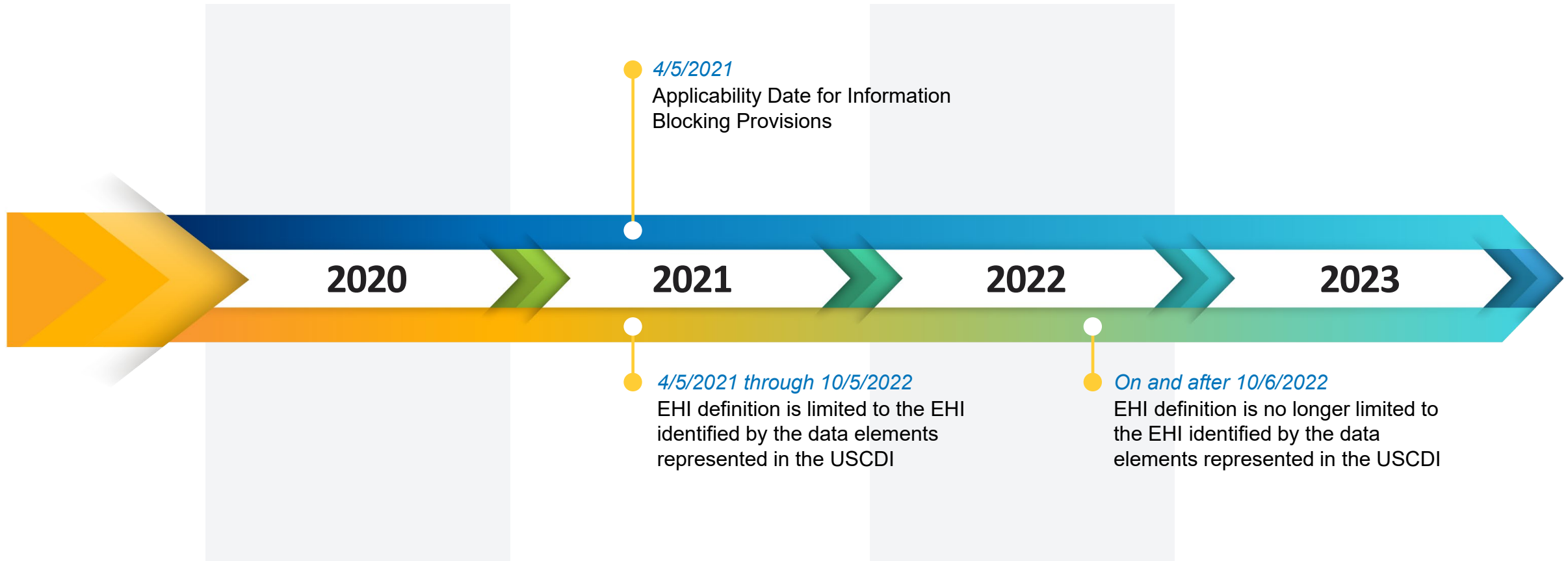
Information Blocking Corrections & Clarifications

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Corrections and Clarifications

We identified certain inadvertent errors in the ONC Cures Act Final Rule, following publication in the Federal Register on May 1, 2020. In the interim final rule, we correct these errors and provide necessary clarifications.

For example, we:

- Clarified that, because part 171 defines information blocking and provides a series of exceptions, it is more accurate to say actors "are subject to" the provisions, rather than "must comply with"
- Clarified that because the phrase "interfere with" is inclusive of "prevent" and "materially discourage," it is unnecessary to include the two latter terms in defining

- the practices that could constitute information blocking
- Clarified that developers subject to the information blocking provisions are health IT developers *of certified health IT*
- Clarified that an actor will "fulfill a *request*" to access, exchange or use EHI, not "fulfill a response"
- Corrected two errors in cross-references

Certification

Conditions and Maintenance of Certification

The 21st Century Cures Act (Section 4002) requires the Secretary of HHS to establish Conditions and Maintenance of Certification requirements for the ONC Health IT Certification Program

The Conditions and Maintenance of Certification express initial requirements and ongoing requirements for health IT developers and their certified Health IT Module(s).

Any noncompliance with the proposed Conditions and Maintenance of Certification requirements would be subject to ONC direct review, corrective action, and enforcement procedures under the ONC Health IT Certification Program.

There are seven Conditions of Certification with accompanying Maintenance of Certification Requirements. They are:

1. **Information Blocking**

2. **Assurances**

3. **Communications**

4. **Application Programming Interfaces (APIs)**

5. **Real World Testing**

6. **Attestations**

7. *(Future) Electronic Health Record (EHR) Reporting Criteria Submission*

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Compliance Date Extensions

Who?

Health IT Developers of Certified Health IT

What?

- 2015 Edition Cures Update certification criteria

- Conditions and Maintenance of Certification requirements

When?

See next slides

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April 5, 2021

Provision		Final Rule
Condition of Certification (CoC) – Information Blocking – (Ạ 170.401)	November 2, 2020	**April 5, 2021**
CoC – Assurances – (Ạ 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	**April 5, 2021**
CoC – Assurances – (Ạ 170.402(a)(2) and (3), and (b)(1)) – Other	Effective date: June 30, 2020	**April 5, 2021**
CoC – Communications – (Ạ 170.403) – Communications requirements, except for Ạ 170.403(b)(1) where we removed the notice requirement for 2020	Effective date: June 30, 2020	**April 5, 2021**
CoC – API – (Ạ 170.404(b)(4)) – Compliance for current API criteria	November 2, 2020	**April 5, 2021**

December 31, 2022

Provision	Final Rule	Interim Final Rule
CoC – API – (Ạ 170.404(b)(3)) – Rollout of new standardized API functionality certified to Ạ 170.315(g)(10)	May 2, 2022	**December 31, 2022**
CoC – Real World Testing – 2015 Edition health IT certification criteria updates – EHI export. See Assurances below	May 2, 2022	**December 31, 2022**

December 31, 2023

Provision	Final Rule	Interim Final Rule
CoC – Assurances – (Ạ 170.402(a)(4) and (b)(2)) – EHI Export Rollout Ạ 170.315(b)(10)	May 1, 2023	**December 31, 2023**

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Begin Annual Cycle One Year Later

Provision	Final Rule	Interim Final Rule
CoC – Communications – (A 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	**Begin annual cycle 1 year later CY 2021**
CoC – *Initial* Attestations – (A 170.406)	April 1-30, 2021 attestation window for attestation period running June 30, 2020 through March 31, 2021	**Begin annual cycle 1 year later April 1-30, 2022**
CoC – Real World Testing – (A 170.405(b)(1) and (2)) – Submit *initial* plan and *initial* results submission	Plan: December 15, 2020 Results: March 15, 2022	**Begin annual cycle 1 year later Initial Plan: December 15, 2021 Initial Results: March 15, 2023**

2015 Edition Cures Update Certification Criteria

Provision	Final Rule	Interim Final Rule
USCDI – Update to the USCDI standard for Ạ 170.315 (b)(1), (b)(2), (e)(1), (f)(5), (g)(6), (g)(9), and (g)(10)	May 2, 2022	**December 31, 2022**
New and Revised Certification Criteria – Update standards or implement for Ạ 170.315 (b)(3), (b)(7), (b)(8), (c)(3), (d)(2), (d)(3), (d)(10), (d)(12), and (d)(13)	May 2, 2022	**December 31, 2022**

New Compliance Dates included in ONC Interim Final Rule

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Certification

6/30/20
General Effective Date, including Cures Update Certification Criteria

4/5/2021
Specific Compliance Requirements Start for Several Conditions of Certification, Including Information Blocking, Assurances, APIs

12/15/2021
Submit Initial Real World Testing Plans

12/31/2022
New HL7® FHIR® API Capability and Other Cures Update Criteria Must Be Made Available

By 12/31/2023
EHI Export Capability Must be Made Available

2020 2021 2022 2023

4/5/2021
Health IT Developers Prohibited From Restricting Certain Communications

4/1/2022
First Attestation to Conditions of Certification Required

3/15/2023
Submit Initial Real World Testing Results

EHI = Electronic Health Information   USCDI = United States Core Data for Interoperability

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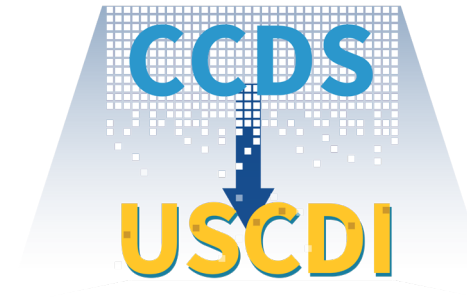
Updated: United States Core Data for Interoperability Standard

The United States Core Data for Interoperability (USCDI) standard will replace the Common Clinical Data Set (CCDS) definition on December 31, 2022.

CCDS → USCDI

USCDI includes the following data classes and data elements:

Provenance   **Clinical Notes**   **Pediatric Vital Signs**   **Address, Email & Phone Number**

Health IT developers need to update their certified health IT to support the USCDI for all certification criteria affected by this change by December 31, 2022.

USCDI updated to USCDI v1 (July 2020 errata)
Made corrections to applicable standards

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US Core Implementation Guide

- We adopted the HL7® FHIR® US Core Implementation Guide STU3 Release 3.1.0 (US Core IG 3.1.0) as part of the ONC Cures Act Final Rule testing and certification requirements for the § 170.315(g)(10) standardized API for patient and population services certification criterion.

- In the interim final rule, we adopt the US Core IG 3.1.1 in § 170.215(a)(2) in order to support industry standardization around the latest version of the US Core IG.

ONC Health IT Certification Program Corrections and Clarifications

Corrections and Clarifications

We identified certain inadvertent errors in the ONC Cures Act Final Rule, following publication in the Federal Register on May 1, 2020. In the interim final rule, we correct these errors and provide necessary clarifications.

For example, we:

- Update the references to "Health IT Modules" in § 170.101 and § 170.200 with "health information technology."

- Update the erroneous reference to "ASTM E1247–18" in the Final Rule with the correct tamper-resistance standard of "ASTM E2147–18," and corresponding errors

- Update the Network Time Protocol standard referenced in the final rule with the current protocol standard

- Correct the "Clinical Quality Measures–Report" criterion to allow a 24 month timeline for compliance

- Correct the term "identify" to "identity" in § 170.315(d)(13)(ii)

- Remove an erroneously included requirement in § 170.315(f)(5)

- Clarify the requirement for native applications and refresh tokens in § 170.315(g)(10)(v)(A)

Summary

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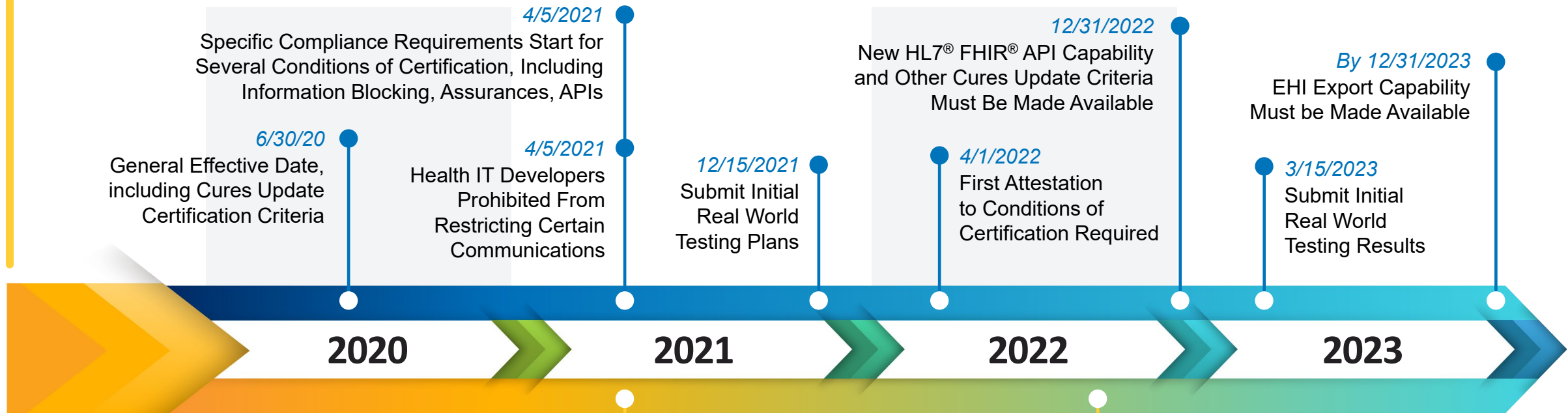Health Information Technology

Important Points

- The information blocking applicability date will move to **April 5, 2021 from November 2, 2020.**

- Many other provisions related to the ONC Health IT Certification Program have been pushed back to December 31, 2022.

- Once the interim final rule is published in the Federal Register, the information blocking provisions and related Conditions of Certification requirements will be **effective immediately**.

- A **60-day comment period** is available for stakeholders to respond to the interim final rule.

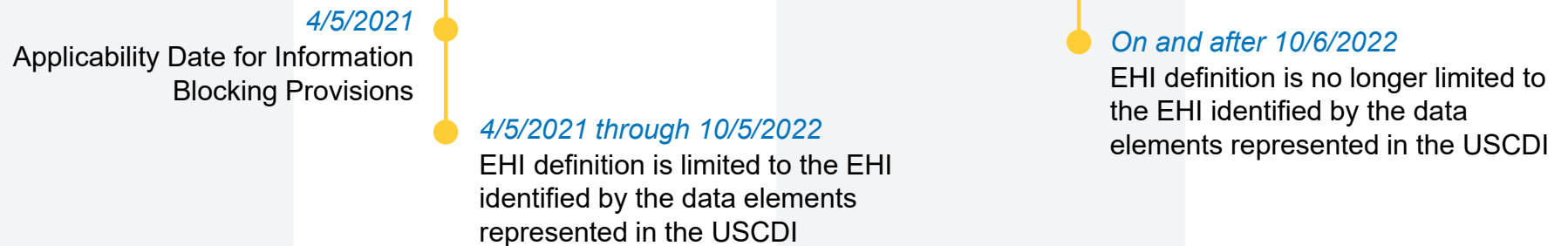# New Applicability/Compliance Dates included in ONC Interim Final Rule

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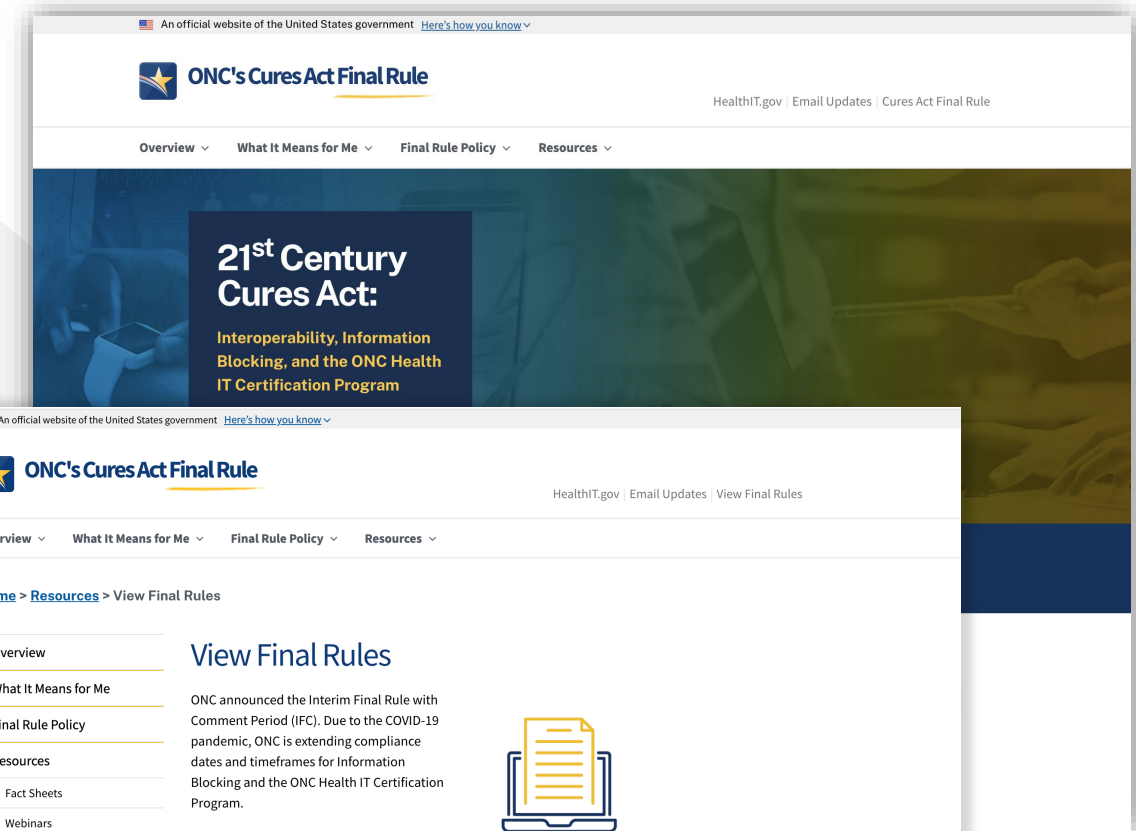
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Information Blocking

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**Please visit
www.healthit.gov/curesrule**

- View the Interim Final Rule

- Fact Sheets

- Additional Resources

Contact ONC

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