

How the 21st Century CURES Act Final Rules Affect Your Organization

presented by

Helen Oscislawski, Esq.

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Attorneys at
Oscislawski LLC

About Helen O.



Helen has recently been selected to the **2020 “Super Lawyers®** list for Health Care Law in New Jersey. The Super Lawyers list is issued by *Thomson Reuters*. Her firm was also included on the 2018, 2019 and 2020 **“Best Law Firms” in Health Care Law**, Princeton, New Jersey list issued by *Best Lawyers*. Links to a description of the selection methodologies used by the organizations issuing these lists can be found [here](#).

Helen is a corporate and regulatory attorney whose practice for over the last 20 years has focused almost exclusively on advising and representing clients in the health care industry. She is the founding member of **Attorneys at Oscislawski LLC**, a progressive and forward-thinking law boutique providing high-quality and cost-effective legal representation to its clients. Helen cemented her reputation as a prominent privacy and health information technology attorney through decades of developed experience and working hand-in-hand with

C-suite executives and in-house general counsels on how to structure and manage complex data-sharing arrangements in compliance with applicable federal and state laws. She is known to many **as a “go to” attorney** for legal guidance and advice on **HIPAA; 42 CFR Part 2; Breach Notification laws**, as well as **state laws regulating the access, use and sharing of medical, health and genetic information**. Helen also has substantial experience with helping her clients navigate legal issues when responding to ransomware attacks, data breaches, OCR audit and complaint letters, and return/sanitization of patient data taken by former employees. On the front end, Helen has completed numerous comprehensive HIPAA legal-gap assessments for health care organizations and business associates, including some of the largest health information exchanges (HIEs) in the tri-state area. In 2008, New Jersey Governor Jon Corzine appointed Helen to the New Jersey Health Information Technology Commission (NJ-HITC) to fill the seat designated by statute for **“an attorney practicing in this State with demonstrated expertise in health privacy.”** N.J.S.A. 26:1A-137(a)2).*[statutorily defined]. In 2010, she was reappointed to NJ-HITC by Governor Christie and tapped to serve as **Chair of the Privacy and Security Committee** for the New Jersey HIT Coordinator. As a trusted advisor, Helen currently represents and advises some of the most cutting edge and sophisticated organizations in the nation, including several large multi-stakeholder collaboratives in the NJ/NY/PA region, as well as a number of burgeoning “big data” innovation projects and initiatives.

Before founding Attorneys at Oscislawski LLC, Helen was a health care attorney with a national law firm for almost a decade where she counseled all types of health care clients on a wide range of legal matters. Helen received her law degree from Rutgers School of Law, with honours, in 1999, and is **admitted in New Jersey (since 1999) and Arizona (since 2020)**. She completed her undergraduate degree at Rutgers University, Douglass College in 1994, with highest honours in her major and high honours overall. She was inducted into **Phi Beta Kappa** upon graduation.

Helen can be reached at helen@oscislaw.com or **609-385-0833** ext.1.

What Are We Going to Cover?

- Background
- Interoperability & Patient Access through API Standards
- “Actors”
- **“Information Blocking”** ↔
- 8 Exceptions:
 1. Preventing Harm
 2. Privacy
 3. Security
 4. Infeasibility
 5. Health IT Performance
 6. Content & Manner
 7. Fees
 8. Licensing
- Penalties
- Compliance Deadlines (3-month enforcement discretion)
- Checklist to Prepare

Impact on HIPAA Policies

- Use & Disclosure of PHI
- Patient Access Requests
- Personal Representatives

Statute & Rules

(plus hyperlinks to source documents)

21st Century CURES Act

-  [Public Law 114-225](#) (December 13, 2016)
-  Information Blocking codified at [42 U.S.C. 300jj-52](#) *et seq.*

ONC Information Blocking & Health IT Certification

-  Proposed Rule, [42 Fed Reg. 7424](#) (March 4, 2019)
-  Final Rule, [85 Fed Reg. 25642](#) (May 1, 2020)

CMS Interoperability & Patient Access

-  Proposed Rule, [84 Fed Reg. 7610](#) (March 4, 2019)
-  Final Rule, [85 Fed Reg. 25510](#) (May 1, 2020)

Impact

★ **Information Blocking** will become **prohibited**

- Healthcare Providers, HIEs/HINs & Developers of *certified* Health IT
- EHI *phased in*
- Penalties and “Appropriate Disincentives”

★ **Patient Access** will become **automated**

- Health IT Developers will conform to **API Standards**
- Patients’ & Plan Members’ Use of **3rd Party Apps**
- Automation of **Patient Access**
- Benefit vs. Risk **Patient Education**
- Federal and state privacy & security requirements

★ **Medicare COP** will drive **Encounter Notification**

- Acute Care, Critical Access, and Psychiatric Hospitals
- Real-time encounter notifications
- EMRs
- “Other Electronic Administrative Systems which conform to content exchange standards found at [45 CFR 170.205\(d\)\(2\)](#)”



The Great Debate



Patient Control

Security



Privacy

“Actors”

3 Categories of Actors

“Health Care Providers”

“Health Information Networks” and
“Health Information Exchanges”

“Health IT Developers of *Certified* Health IT”

Health Care Provider

Public Health Service Act (42 U.S.C. 300jj)

- Hospitals
- Skilled Nursing Facilities
- Nursing Facilities
- Home Health Entities
- *Other* Long Term Care Facilities
- Health Care Clinics
- Community Mental Health Centers
- Renal Dialysis Facilities
- Blood Centers
- Pharmacies
- Laboratories
- Ambulatory Surgical Centers
- FQHCs
- Rural health clinic
- Covered Entities under 42 U.S.C. 256b
- EMS Providers
- Group Practices
- Pharmacists
- Physicians
- Practitioners
- Therapists
- Providers operated by or under contract with the Indian Health Service or by an Indian tribe, tribal organization, or urban Indian organization
- ***Any other category*** of health care facility, entity, practitioner, or clinician ***determined appropriate by the HHS***

Health Information Networks and Health Information Exchanges

And individual or entity that **determines, controls**, or has the **discretion to administer** any requirement, policy, or agreement that permits, enables, or requires the use of any technology or services for **access, exchange, or use of EHI**:

- Among *more than two* “**unaffiliated**” individuals or entities that are enabled to exchange EHI with each other;

and

- That is for a **treatment, payment, or health care operations**

Health IT Developer of Certified Health IT

An individual or entity

-- other than a health care provider that *self-develops* health IT for its own use –

- That **develops** or **offers** health information technology

and

- Has one or more Health IT Modules **certified** under a program for the **voluntary certification** by ONC's Health HIT Certification Program

“Information Blocking”

21st Century CURES Act Defined

- ❖ Likely to
 - × *Interfere With*
 - × *Prevent*
 - × *Materially Discourage*

access, exchange, or use of EHI

Two Knowledge Standards:

- ❖ **Health IT Developer** or **HIE/HIN** knows or **should know** that such practice is ***likely to*** interfere with, prevent, or materially discourage the access, exchange, or use of EHI
- ❖ **Healthcare Provider** **knows** that such practice is ***unreasonable*** **and** is ***likely to*** interfere with, prevent, or materially discourage access, exchange, or use of EHI

“May Include” Following

- ✘ Practices that **restrict** authorized access, exchange, or use under applicable state or federal law of such information **for Treatment** and **other Permitted Purposes** under such applicable law, including transitions between certified Health IT
- ✘ Implementing Health IT in **nonstandard ways** that are likely to substantially **increase the complexity or burden** of accessing, exchanging, or using EHI
- ✘ Implementing Health IT in ways that are likely to:
 - ✘ **Restrict** the access, exchange, or use of EHI with respect to **exporting** complete information sets or in transitioning between Health IT systems;
 - OR -
 - ✘ Lead to fraud, waste, or abuse, or **impede innovations** and **advancements** in health information access, exchange, and use, including care delivery enabled by Health IT.



Final Rule clarifies “*to Interfere With*”

- ✓ **Actors NOT required to violate BAAs or SLA**
 - **BUT**, agreements *could constitute an interference* if used in a ***discriminatory manner*** to limit or prohibit the access, exchange, or use of EHI for Treatment that otherwise would be permitted by HIPAA

- ✓ **Educating** patients or plan members about the **privacy** and **security risks posed by the Apps** they choose to receive their EHI would **NOT** be considered an “interference with.”

3rd Party Apps: Minimum Privacy Policies & Practices

- ☑ Made **publicly accessible** at all times, including updated versions
- ☑ **Shared with all individuals** that use the technology prior to the technology's receipt of EHI from an actor
- ☑ Written in **plain language** and in a manner calculated to inform the individual who uses the technology
- ☑ **Includes a statement** of whether and how the individual's EHI may be **accessed, exchanged, or used by any other person or other entity**, including **whether** the individual's EHI may be **sold at any time** (including in the future)
- ☑ Includes a requirement for **express consent** from the individual **before** the individual's EHI is accessed, exchanged, or used, including receiving the individual's express consent before the individual's EHI is sold (other than disclosures required by law or disclosures necessary in connection with the sale of the application or a similar transaction)

8 Exceptions (“Safe Harbors”)

**Exceptions Allowing Actors to NOT Fulfill
Requests for EHI Access, Exchange & Use:**

- 1. Preventing Harm**
- 2. Privacy**
- 3. Security**
- 4. Infeasibility**
- 5. Health It Performance**

Exception #1: *Preventing Harm*

- ❑ Actor must hold a *reasonable belief* that the practice will *substantially reduce* a risk of harm
- ❑ Actor's practice must be *no broader than necessary*
- ❑ Actor's practice must satisfy at least one condition from each of the following categories:
 - Type of Risk
 - Type of Harm
 - **Implementation Basis** (organizational policy vs determination specific to the facts and circumstances)
- ❑ The practice must satisfy the condition concerning a *patient right to request review* of an individualized determination of risk of harm

Exception #2: *Privacy*

- ❑ ***Precondition not satisfied:*** If an actor is **required by a state or federal law to satisfy a precondition** (such as a patient consent or authorization) prior to providing access, exchange, or use of EHI, the actor may choose not to provide access, exchange, or use of such EHI if the precondition has not been satisfied under certain circumstances
- ❑ ***Health IT developer of certified health IT not covered by HIPAA:*** If an actor is a health IT developer of certified health IT that is not required to comply with the HIPAA Privacy Rule, the actor may choose to interfere with the access, exchange, or use of EHI for a privacy-protective purpose if certain conditions are met
- ❑ ***Denial of an individual's request for their EHI consistent with 45 CFR 164.524(a) (1) and (2):*** An actor that is a covered entity or business associate may deny an individual's request for access to his or her EHI in the circumstances provided under 45 CFR 164.524(a)(1) and (2) of the HIPAA Privacy Rule.
- ❑ ***Respecting an individual's request not to share information:*** An actor may choose not to provide access, exchange, or use of an individual's EHI if doing so fulfills the wishes of the individual, provided certain conditions are met.



Exception #3: *Security*

- ❑ The practice must be:
 - ❑ *Directly related to* safeguarding the confidentiality, integrity, and availability of EHI;
 - ❑ *Tailored* to specific security risks;

and

- ❑ Implemented in a *consistent and non-discriminatory* manner

Exception #4: *Infeasibility*

- ❑ ***Uncontrollable events***: Actor cannot fulfill the request for access, exchange, or use of EHI due to a natural or human-made disaster, public health emergency, public safety incident, war, terrorist attack, civil insurrection, strike or other labor unrest, telecommunication or internet service interruption, or act of military, civil or regulatory authority.
- ❑ ***Segmentation***: Actor cannot fulfill the request for access, exchange, or use of EHI because the actor cannot unambiguously segment the requested EHI.
- ❑ ***Infeasibility under the circumstances***: Actor demonstrates through contemporaneous written record or other documentation its consistent and non-discriminatory consideration of certain factors that led to its determination that complying with the request would be infeasible under the circumstances.

Exception #5: *Health IT Performance*

- ❑ The practice must:
 - ❑ Be implemented for a period of time **no longer than necessary** to achieve the **maintenance or improvements** for which the health IT was made unavailable or the health IT's performance degraded;
 - ❑ Be implemented in a consistent and non-discriminatory manner; and
 - ❑ Meet certain requirements if the unavailability or degradation is initiated by a health IT developer of certified health IT, HIE, or HIN

- ❑ Actor may take action against a third-party app that is **negatively impacting the health IT's performance**, provided that the practice is:
 - For a period of time no longer than necessary to resolve any negative impacts;
 - Implemented in a consistent and non-discriminatory manner; and
 - Consistent with existing service level agreements, where applicable



Exceptions with Procedures for fulfilling requests for EHI Access, Exchange & Use:

- 1. Consent & Manner**
- 2. Fees**
- 3. Licensing**

Exception #6: *Content & Manner*

❖ Content

- ❖ Up to 24 months after the publication date of the Cures Act final rule, Actor must **only** respond to a request to access, exchange, or use EHI identified by the data elements represented in the **USCDI standard**
- ❖ 24 months after May 2, 2020, Actor **must** respond to a request to access, exchange, or use of **FULL EHI** (defined in § 171.102)

❖ Manner

- ❖ Actor **may** fulfill a request in an **alternative manner** when:
 - Technically unable to fulfill the request in any manner requested; or
 - Cannot reach agreeable terms with the requestor to fulfill the request.
- ❖ If alternative manner used, such fulfillment must comply with the order of priority described in the manner condition and must satisfy the Fees Exception and Licensing Exception, as applicable

Exception #7: Fees

- ❖ **Meet the basis for fees condition.** Fees an Actor charges must:
 - Be based on **objective and verifiable criteria** that are uniformly applied for all similarly situated classes of persons or entities and requests.
 - Be **reasonably related** to the Actor's costs of providing the type of access, exchange, or use of EHI.
 - **NOT be based on** whether the requestor or other person is a **competitor, potential competitor**, or will be using the EHI in a way that **facilitates competition** with the actor.

- ❖ Exception does not apply to:
 - Fee based in any part on the **electronic access by an individual**, their personal representative, or another person or entity designated by the individual to access the individual's EHI
 - Fee **to perform an export** of EHI via the capability of certified Health IT

Exception #8: *Licensing*

- Actor must begin license negotiations with the requestor ***within 10 business*** days from receipt of the request and ***negotiate a license within 30 business days*** from receipt of the request
- **Licensing conditions:**
 - Scope of rights
 - Reasonable royalty
 - Non-discriminatory terms
 - Collateral terms
 - Non-disclosure agreement
- Additional conditions relating to the provision of interoperability elements

Penalties

Health Care Providers

“Shall be referred to the appropriate agency to be subject to *appropriate disincentives*”

HIEs, HINs & Health IT Developers

- May not exceed **\$1,000,000 per violation**
- Such determination **shall** take into account factors such as the ***nature*** and ***extent*** of the information blocking and ***harm*** resulting from such information blocking, including, where applicable:
 - the number of patients affected
 - the number of providers affected
 - the number of days the information blocking persisted

“Single” Violation

- A health care provider notifies its health IT developer of its intent to switch to another EHR system and requests a complete **electronic export** of its patients’ EHI via the capability certified to in 45 C.F.R. 170.315(b)(10). The developer refuses to export any EHI without charging a fee. The ***refusal to export EHI without charging this fee would constitute a single violation.***
- A health IT developer (D1) connects to a health IT developer of certified health IT (D2) using a certified API. D2 decides to disable D1’s ability to exchange information using the certified API. D1 requests EHI through the API for one patient of a health care provider for treatment. As a result of D2 disabling D1’s access to the API, D1 receives an automated denial of the request. ***This would be considered a single violation.***



“Multiple” Violations

Health IT developer’s software license agreement with one customer **prohibits the customer from disclosing to its IT contractors certain technical interoperability information** without which the customer and the IT contractors **cannot access and convert EHI for use in other applications**

Health IT developer also chooses **to perform maintenance** on the health IT that it licenses to the customer at the **most inopportune times** because the customer has indicated its intention to switch its health IT to that of the developer’s competitor

- ✘ Violation #1 = contractual prohibition on disclosure of certain technical interoperability information
- ✘ Violation #2 = performing maintenance on the health IT in a discriminatory fashion

“Multiple” Violations

Health IT developer requires **vetting of third-party applications** before the applications can access Health IT developer’s product

Health IT developer **denies applications based on the functionality** of the application.

- ✘ Multiple violations based on **each instance** Health IT developer vets a third-party application. Each practice is separate and based on the specific functionality of each application. Each of the violations in this specific scenario would be subject to a penalty.

Compliance Deadlines

Enforcement Discretion due to COVID-19

www.healthit.gov/curesrule/resources/enforcement-discretion



ONC's Cures Act Final Rule

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Enforcement Discretion

Pursuant to the 21st Century Cures Act, ONC is tasked with updating the ONC Health IT Certification Program (Program). The ONC Cures Act Final Rule (21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Final Rule) includes new conditions and maintenance of certification requirements that developers certified under the Program are required to meet. One requirement of developers of application programming interfaces (APIs) is to make available standardized APIs that will aid in patient access to their health information on a smartphone. As an additional example, health IT developers of interoperable technology must real-world test their certified products to improve performance reliability in care settings.

In light of COVID-19, ONC will exercise its discretion in enforcing all new requirements under 45 CFR Part 170 that have compliance dates and timeframes until 3 months after each initial compliance date or timeline identified in the ONC Cures Act Final Rule. [View Enforcement Discretion Dates and Timeframes \(PDF - 177 KB\)](#) This additional flexibility for development and implementation enables our healthcare system to focus on addressing the COVID-19 pandemic, while still maintaining a trajectory that will advance patients' access to their health information, reduce the cost of care, and improve the quality of care.



Health IT Certification

www.healthit.gov/cures/sites/default/files/cures/2020-04/Enforcement_Discretion.pdf

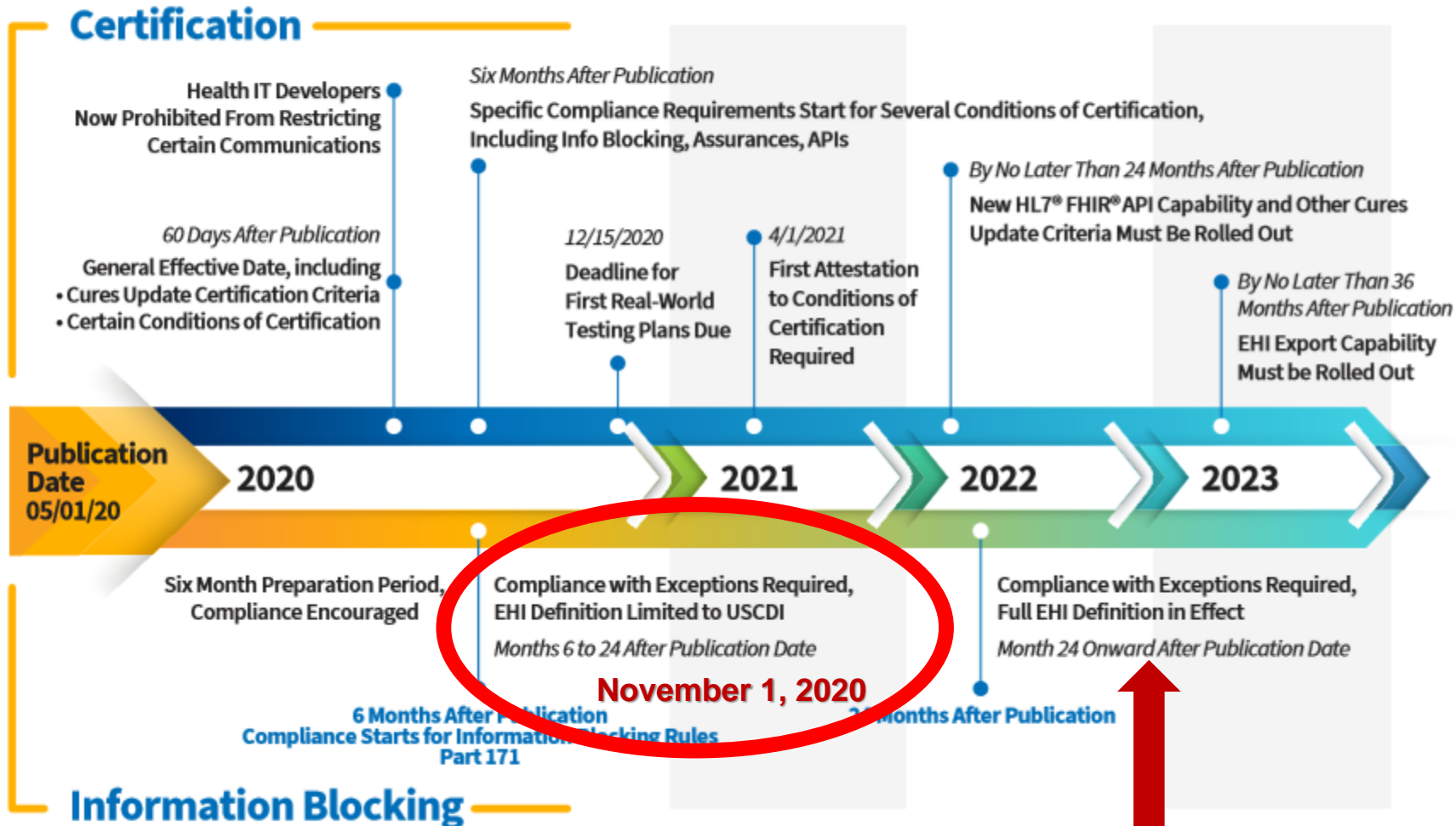
The Office of the National Coordinator for
Health Information Technology

 CERTIFICATION

CURES ACT FINAL RULE

Enforcement Discretion Dates and Timeframes

Provision	Compliance Date/Timeframe	Enforcement Discretion Date/Timeframe
Condition of Certification (CoC) – Information Blocking	6 months after final rule publication	3 months after the compliance timeframe
CoC – Assurances – Will not take any action that constitutes information blocking or actions that inhibit access, exchange, and use of electronic health information (EHI)	6 months after final rule publication	3 months after the compliance timeframe
CoC – Assurances – EHI Export Rollout	36 months after final rule publication	3 months after the compliance timeframe
CoC – Assurances – Other	Effective date of final rule	3 months after the compliance date
CoC – Communications – 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
CoC – Communications – Other	Effective date of final rule	3 months after the compliance date
CoC – Application Programming Interface (API) – Compliance by Certified API Developers with health IT certified to current API criteria	6 months after final rule publication	3 months after the compliance timeframe
CoC – API – Rollout of new standardized API functionality	24 months after final rule publication	3 months after the compliance timeframe
CoC – Real World Testing (RWT) – Submit initial plan and initial results submission	Plan: December 15, 2020 Results: March 15, 2022	Generally remains the same, except for initial cycle for the annual submissions 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
CoC – RWT – Updates to United States Core Data for Interoperability (USCDI)	24 months after final rule publication	3 months after the compliance timeframe
CoC – Initial Attestations	April 1-30, 2021 attestation window for attestation period running from the effective date of final rule through March 31, 2021	Generally remains the same except for the initial attestation, which will now be accepted through July 30, 2021



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

USCDI Standard

(United States Core Data for Interoperability)

- **USCDI** = standardized set of health data classes and constituent data elements for nationwide, interoperable health information exchange
- USCDI “**Data Class**” = aggregation of various Data Elements by a common theme or use case
- USCDI “**Data Element**” = most granular level at which a piece of data is exchanged. (Ex., Date of Birth is a Data Element rather than its component Day, Month, or Year, because Date of Birth is the unit of exchange)
- USCDI **replaces** CCDS in the following certification criteria:
 - “Transitions of Care”
 - “Clinical Information Reconciliation & Incorporation,” *BUT only 3 data elements:*
 - Medications
 - Medication Allergies
 - Problems List
 - “View, Download, and Transmit To 3rd Party”
 - “Transmission To Public Health Agencies” – *electronic case reporting*
 - “Consolidated CDA Creation Performance”
 - “Application Access” – *all data request*
- USCDI standard is **required** as part of the new API certification criteria

USCDI v1 Summary of Data Classes and Data Elements

Allergies and Intolerance

- Substance (Medication)
- Substance (Drug Class)
- Reaction

Assessment and Plan of Treatment

Care Team Members

Clinical Notes

- Consultation Note
- Discharge Summary Note
- History & Physical
- Imaging Narrative
- Laboratory Report Narrative
- Pathology Report Narrative
- Procedure Note
- Progress Note

Goals

- Patient Goals

Health Concerns

Immunizations

Laboratory

- Tests
- Values/Results

Medications

- Medications
- Medication Allergies

Patient Demographics

- First Name
- Last Name
- Previous Name
- Middle Name (including middle initial)
- Suffix
- Birth Sex
- Date of Birth
- Race
- Ethnicity
- Preferred Language
- Current Address
- Previous Address
- Phone Number
- Phone Number type
- Email Address

Problems

Procedures

Provenance

- Author Time Stamp
- Author Organization

Smoking Status

Unique Device Identifier(s) for a Patient's Implantable Device(s)

Vital Signs

- Diastolic Blood Pressure
- Systolic Blood Pressure
- Body Height
- Body Weight
- Heart Rate
- Respiratory Rate
- Body Temperature
- Pulse Oximetry
- Inhaled Oxygen Concentration
- BMI Percentile (2-20 years)
- Weight-for-length Percentile (Birth - 36 months)
- Head Occipital-frontal Circumference Percentile (Birth - 36 months)

Summary of Changes

<i>Proposed USCDI</i>	<i>Final ONC Rule (USCDI v1)</i>
Patient Demographics <ul style="list-style-type: none">• Address	Patient Demographics <ul style="list-style-type: none">• Current Address• Previous Address• Phone Number• Phone Number Type• Email
Provenance <ul style="list-style-type: none">• Author• Author Organization• Author Time Stamp	Provenance <ul style="list-style-type: none">• Author Organization• Author Time Stamp
Substance Reactions (incl. Medication Allergies) <ul style="list-style-type: none">• Substance• Reaction	Allergies & Intolerances <ul style="list-style-type: none">• Substance (Medication)• Substance (Drug Class)• Reaction

Checklist to Prepare

(Health Care Providers & HIEs/HINs)

- Identify systems and data-sharing arrangements that are sources for **access, exchange, or use** of EHI

- Focus first on USCDI Data Classes & Data Elements (Nov 2, 2020 compliance deadline)

- Review and Update HIPAA P&Ps re:
 - Patient Access**
 - Uses & Exchange** of USCDI/EHI for TPO

- Incorporate **8-Exceptions**
 - Must** be *organization-wide* policy
 - Must** *train* employees

- Develop **P&P for Case-by-Case** response procedures to data-request and Info-Blocking analysis. Document.

Thank you!

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Attorneys at
Oscislawski LLC

Helen Oscislawski, Esq.
Principal, Attorneys at Oscislawski LLC
helen@oscislaw.com
609-835-0833

