

Cures Act Overview

Nicholas Loftin, Director, Virtual Care, Pivot Point Consulting November 10, 2021

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- This presentation is for informational purposes only.
- It does NOT, and is not intended to, constitute legal advice.
- Only your attorney can provide assurances regarding the application of this information to your particular circumstances.
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About the Empowering Patients Educational Series

- Designed to support CHCANYS members as they work toward compliance with information blocking regulations stemming from the 21st Century Cures Act
- November 2021-March 2022
- Includes:
 - Webinar presentations providing foundational knowledge for all member roles (provider, compliance, HIM)
 - Ask the Experts interactive Q&A sessions focusing on information needs of specific member roles
 - Supporting resources to help members operationalize the regulations within their organizations



Today's Learning Objectives

Cures Act Final Rule 101

Future webinars will go into additional detail (102 and beyond!)

This presentation will enable you to:

- Understand and employ Cures Act terminology
- Describe how the Cures Act impacts your organization and your role
- Articulate requirements for compliance and penalties of noncompliance
- Identify additional Cures Act-related resources to support your organization



Today's Topics

- Terminology
- What is the Cures Act?
- Why do I need to know about the Cures Act?
- What do I need to know about the Cures Act?
- Q&A
- What's next in the series?





Industry Voices-Hospital staff unprepared for information blocking rules. It's time to invest in education, training

by Matthew Michel



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■ Why the new U.S. interoperability rules matter during the COVID-19 pandemic

ONC Launches USCDI Initiative to Improve Dataset Interoperability

ONC will aim to improve dataset interoperability and alignment standards and identify specific datasets for federal partners with the USCDI+ initiative.

Why The 21st Century Cures Act is an Innovators Dream

Provisions in the Cures Act Final Rule represent huge advances in patient empowerment, freedom, convenience, and unprecedented accessibility.

Behind the scenes: How health systems, EHR vendors will give patients unprecedented access to their data

■ Many Healthcare Organizations Aren't Ready for the Now Enforced ONC Cures Act Final Rule



April 18, 2021

Briana Contreras

Terminology

- Information Blocking
 - If conducted by a health provider, a practice likely to interfere with, prevent or materially discourage access, exchange or use of electronic health information (EHI) when the provider knows that such practice is unreasonable and is likely to interfere with, prevent or materially discourage access, exchange or use of EHI
- Exceptions
 - Eight ONC-defined allowable methods of information blocking (see Appendix for list)
- Actor
 - Any individual or technology in a healthcare organization that interacts with the patient's ePHI
- Third-Party Application
 - An external platform used by patients and providers to receive and transfer a patient's electronic health information
- Certified Health IT
 - A health IT solution that has been certified by the ONC to meet the requirements for interoperability and information blocking
- Vendor
 - An external entity that delivers goods and services to the healthcare organization and to patients on behalf of the healthcare organization



Terminology

- Health IT developer
 - A vendor that develops and delivers software and hardware for the healthcare organization to facilitate patient care
- Health Information Network (HIN)/ Health Information Exchange (HIE)
 - The process and technology that enables electronic information sharing among disparate health providers, patients, and payers securely
- Designated Record Set
 - The set of information that a patient is required to have access to, such as medical and billing records, case management and health plan enrollment
 - Records that are "to make decisions about individuals" also are included; this definition is not fully defined by the ONC
- Electronic Health Information (EHI)/Electronic Protected Health Information (ePHI)
 - Patient demographic and clinical information that is contained in an electronic format
- Interoperability
 - The ability for disparate health IT systems to communicate using connectivity methods such as API, HL7 and FHIR to transfer USCDI data elements
- United States Core Data for Interoperability (USCDI)
 - A nationally defined list of data elements contained within a patient's record that are required to be available to share with other certified health information technologies (see Appendix for full list of data elements as of 11/10/21)



What is the Cures Act?

- What is the Cures Act Final Rule?
 - Legislation Title: Office of the National Coordinator for Health information Technology (ONC), Department of Health and Human Service (HHS) 21st Century Cures Act Final Rule
 - AKA: 45 CFR 170 and 45 CFR 171
 - Full legislation language located <u>here</u>
- Why was it enacted?
 - Designed to advance interoperability and address occurrences of information blocking to empower patients and ease the ability for patients to access their own medical records



What is the Cures Act?

- People (roles) it applies to
 - YOU: Any individual that interacts with the patient chart/electronic health record
- Which organizations are impacted?
 - All healthcare delivery organizations (hospitals, ambulatory clinics, etc.)
 - Healthcare IT platforms such as EMRs (Epic, NextGen, ECW, Athena, etc.)
 - Insurance/payer organizations



Why do I need to know about the Cures Act?

- Penalties of up to \$1 million per offense of information blocking
 - Timelines for financial penalties under development
- Compliance timeline
 - Final Rule delivered 6/30/2020
 - Enforcement for healthcare delivery organizations began 4/5/2021
 - We are now past the initial enforcement deadline organizations should be compliant as of 4/5/2021
- How does the Cures Act relate to HIPAA?
 - HIPAA is intended to protect the privacy of a patient, whereas the Cures Act enables the sharing of patient information with the patient and other health providers



What do I need to know about the Cures Act?

- How to become compliant and stay compliant
 - Ensure understanding across the organization of the Final Rule and the eight exceptions
 - Ensure policies, procedures and workflows meet new Cures Act requirements
 - Validate that your technology is compliant with the Final Rule by updating to most recent version
- Who needs to be involved
 - All employees have a role to play with the Cures Act
 - Key stakeholders: Compliance, Medical Records, Providers, IT/EMR team



What do I need to know about the Cures Act?

- Specific actions to take
 - Upgrade EMR to most recent version to ensure technology compliance
 - Need direct conversation with vendor to determine workflow allowances
 - Deliver internal training to key end users to ensure all individuals have appropriate knowledge level
 - Review and update Policies and Procedures relevant to delivery of patient information



Educational Series Schedule

Additional Ask the Experts sessions will be scheduled based on member interest. We welcome your suggestions! HCCN@chcanys.org

Month	Topic	Webinar Date	Ask the Experts (ATE) Date(s)	
November 2021	Cures Act Overview	Wed, Nov 10 Noon-1 ET	All roles Wed, Nov 17 Noon-1 ET	
December	OpenNotes Overview	Wed, Dec 1 Noon-1 ET	Providers Wed, Dec 15 Noon-1 ET	
January 2022	Information Blocking Exceptions	Wed, Jan 12 Noon-1 ET	Compliance, HIM Tue, Jan 18 Noon-1 ET	
February	Preparing for Cures Act Compliance, Part 1 (organizational readiness)	Wed, Feb 16 Noon-1 ET	Compliance, HIM, IT Wed, Feb 23 Noon-1 ET	
March	Preparing for Cures Act Compliance, Part 2 (communication of records)	Wed, Mar 16 Noon-1 ET	Providers Wed, Mar 23 Noon-1 ET	Compliance, HIM, IT Wed, Mar 23 Time TBD



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Appendix



Information Blocking Exceptions

Preventing Harm

• If the actor has a reasonable belief that releasing information will lead to harm toward the patient or other associated individual, relevant information can be withheld/blocked without penalty

Privacy

 If releasing information will cause a risk to maintaining the patient's privacy, the information can be withheld/blocked without penalty

Security

 If releasing information will cause a risk to maintaining the security, the information can be withheld/blocked without penalty

Infeasibility

• If the request for records has legitimate practical challenges preventing the ability to comply, such as technical or legal impediments, information can be blocked/withheld without penalty



Information Blocking Exceptions

Health IT Performance

• If an actor is unable to comply with a request for records due to temporary downtime of health IT, information can be blocked/withheld without penalty

Content and Manner

 If an actor is unable to comply with the deliver manner or platform requested, information can be blocked/withheld without penalty

Fees

 It is not information blocking if an actor charges reasonable fees for access to the requested health information

Licensing

• It is not information blocking if an actor requires interoperability licenses for access to the requested health information



USCDI-Required Data Elements

First name	Last name	Previous name	Middle name (including middle initial)	Suffix
Sex (assigned at birth)	Sexual orientation	Gender identity	Date of birth	Race
Ethnicity	Preferred language	Current address	Previous address	Phone number
Phone number type	Email Address	Smoking Status	Medications	Patient Goals
SDoH goals	Health concerns	Immunizations	Procedures	SDoH Interventions
Laboratory tests	Laboratory values/results	Diagnostic imaging tests	Diagnostic imaging results/reports	Clinical tests
Clinical test results/report	Problems	SDoH Problems/health concerns	Date of diagnosis	Date of resolution
Allergies and intolerances- substance (medication)	Allergies and intolerances- Substance (drug class)	Allergies and intolerances- reaction	Assessment and plan of treatment	SDoH Assessment
Care team member name	Care team member identifier	Care team member role	Care team member location	Care team member telecom
Unique device identifiers for patient's implantable devices	Encounter type	Encounter diagnosis	Encounter time	Encounter location
Encounter disposition	Diastolic blood pressure	Systolic blood pressure	Body Height	Body weight
Heart Rate	Respiratory rate	Body temperature	Pulse oximetry	Inhaled Oxygen Concentration
Weight-for-length percentile (Birth-36 months)	Head-occipital-frontal circumference percentile (birth-36 months)	BMI Percentile (2-20 years)		

