

What Clinicians and Other Health Care Providers Need to Know

An Introduction to Information Sharing Under the Information Blocking Regulations

September 14, 2021



General Disclaimers

- **The information in this presentation is based on the regulations in 45 CFR Part 171.**
- While every effort has been made to ensure accuracy, this presentation is not a legal document. Please note that other federal, state and local laws may apply.
- Examples are merely illustrative and may be simplified for ease of discussion.
- Any practice (act or omission) that implicates the information blocking regulations may come under investigation by HHS.
- This communication is produced and disseminated at U.S. taxpayer expense.

Welcome

Introductory Remarks from the National Coordinator

Micky Tripathi, PhD, MPP



Speakers



Elise Sweeney Anthony
Executive Director of Policy
Office of Policy
HHS/ONC



Thomas Mason, MD
ONC Chief Medical Officer
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Director, Compliance & Administration
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Implementing the 21st Century Cures Act

Some Benefits of Information Sharing

Patients

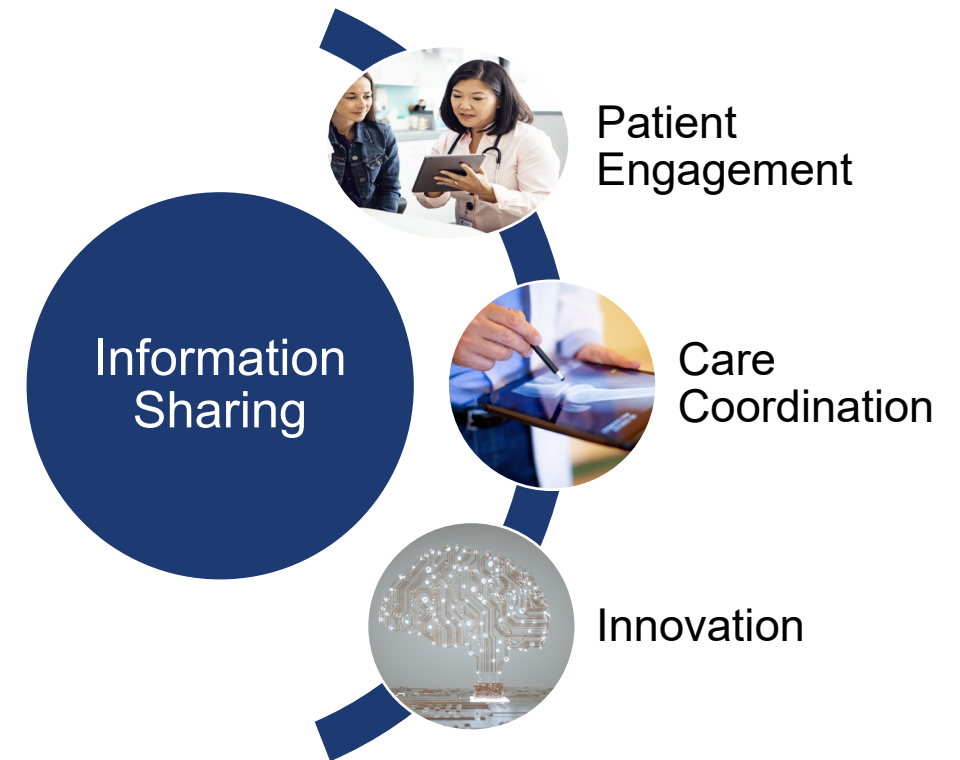
- ✓ Improves patient engagement
- ✓ Easier access to health information
- ✓ Privacy preferences remain respected

Clinicians & Other Health Care Providers

- ✓ Improves access to information to deliver the best care
- ✓ Improves care coordination
- ✓ Improves choice of software

Health IT Developers

- ✓ Encourages innovation to lessen burden
- ✓ Enhances the value of technology to clinicians and other health care providers



Learning Objectives

- Define information blocking
 - Identify electronic health information (EHI)
 - Identify a potential interference
 - Identify the eight exceptions
- Describe enforcement roles and timeline
- Learn how to report information blocking
- Identify where to find more information

The 21st Century Cures Act

Section 4004: Information Blocking

- Defines “information blocking”
- Authorizes the Secretary to identify reasonable and necessary activities that do **not** constitute information blocking
- Tasks **ONC** to implement a standardized process for reporting information blocking claims
- Tasks the HHS Office of Inspector General (**OIG**) with investigating claims of information blocking
- Prescribes sanctions for information blocking

What is “information blocking”?

Definition

(a) Information blocking means **a practice** that—

(1) **Except as required by law** or covered by an exception, is likely to **interfere with** access, exchange, or use of **electronic health information** (EHI); and

(2) If conducted **by a health information technology developer of certified health IT, health information network or health information exchange**, such developer, network or exchange **knows, or should know**, that such practice is likely to interfere with access, exchange, or use of EHI; or

(3) If conducted by a **health care provider**, such provider **knows** that such practice is unreasonable and is likely to interfere with the access, exchange, or use of EHI.

(b) Until date specified in 45 CFR 171.103(b), EHI for purposes of § 171.103(a) is limited to the **EHI identified by the data elements represented in the USCDI** standard adopted in § 170.213.

Elements of Information Blocking

- Not “required by law”
- Not covered by an exception
- Likely to “interfere with” access, exchange, or use
- Electronic health information (EHI)
- By a health information technology developer, HIE/HIN, or provider (an information blocking “actor”)
- Actor has requisite knowledge

Interfere with or ***interference*** means to prevent, materially discourage, or otherwise inhibit.

What is “Electronic Health Information”?

- Electronic Health Information (EHI) is **electronic protected health information (ePHI)** that **would be** included in a **designated record set**, regardless of whether it is maintained by or for an “actor” required to comply with HIPAA.
- **Until October 6, 2022, United States Core Data for Interoperability (USCDI)** describes what electronic health information is within scope for the information blocking regulations.
 - Any data represented by data elements described within USCDI is in-scope for information blocking **now**.
 - Does **not** limit EHI to what is recorded or exchanged consistent with any specific interoperability standard.
- **Note:** EHI excludes (now and after October 5, 2022):
 - Psychotherapy notes; or
 - Information compiled in reasonable anticipation of legal proceedings.

Key Dates	EHI for information blocking purposes is . . .
4/5/2021 through 10/5/2022	Limited to EHI identified by the data elements represented in the USCDI v1
On and after 10/6/2022	No longer limited to EHI identified by the data elements represented in the USCDI v1

Data Elements Represented in USCDI v1

Allergies and Intolerances

- 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 Narrative Report
- Pathology Report Narrative
- Procedure Note
- Progress Note

Goals

- Patient Goals



Health Concerns



Immunizations



Laboratory

- Tests
- Values/Results



Medications



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)

www...

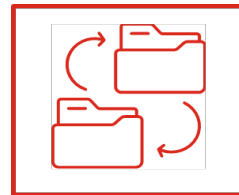
For more info:

HealthIT.gov/USCDI

What individuals and entities are subject to the information blocking regulations (“actors”)?



Health IT Developers of Certified Health IT



Health Information Networks (HINs)
& Health Information Exchanges (HIEs)



Health Care Providers

Fact Sheet Defining Health Care Providers:

https://www.healthit.gov/cures/sites/default/files/cures/2020-08/Health_Care_Provider_Definitions_v3.pdf

Which health care providers are covered by the information blocking regulations?

Frequent Questions

- I am a pharmacist. Am I considered a health care provider subject to the information blocking regulations?
- Is a clinician, hospital, or other type of provider who does not participate in Medicare or Medicaid still an “actor” under the information blocking regulations?
- Are clinicians and health care providers who do not use any certified health IT subject to the information blocking regulations?

Resources:

- ONC’s [Information Blocking FAQs](#) on HealthIT.gov
- ONC Information Blocking [Health Care Provider Definition Fact Sheet](#)

Health Care Providers

42 U.S. Code § 300jj

- hospital
- skilled nursing facility
- nursing facility
- home health entity or other long term care facility
- health care clinic
- community mental health center
- renal dialysis facility
- blood center
- ambulatory surgical
- emergency medical services provider
- federally qualified health center
- group practice
- pharmacist
- pharmacy
- laboratory
- physician
- practitioner
- rural health clinic
- ambulatory surgical center
- a therapist
- a provider operated by, or under contract with, the Indian Health Service or by an Indian tribe, tribal organization, or urban Indian organization
- a “covered entity” under certain statutory provisions
- any other category of health care facility, entity, practitioner, or clinician determined appropriate by the Secretary

Information Blocking and Practices “Required by Law”

- The information blocking definition does not include practices that are required by law. Law would include:
 - Statutes, regulations, court orders, and binding administrative decisions or settlements, such as those from the Federal Trade Commission (FTC) or the Equal Employment Opportunity Commission (EEOC).
 - Federal, State and Tribal laws, as applicable.

* “Practices” will be evaluated on a case-by-case basis to determine whether information blocking has occurred. A practice likely to be an interference may not be information blocking if the actor’s practice is required by law, satisfies the conditions of an exception, or is done without the knowledge required on the part of the actor by the information blocking definition.

Are there any exceptions?

- The norm is to avoid actions or omissions (“practices”) that are likely to interfere with information sharing.
- Regulations have established eight “exceptions” offering assurance that the reasonable and necessary “practices” they cover will **not** be considered information blocking.

Applicable to delaying, restricting, or denying access, exchange, or use

1. Preventing Harm Exception
2. Privacy Exception
3. Security Exception
4. Infeasibility Exception
5. Health IT Performance Exception

Procedures for fulfilling access, exchange, or use of EHI

6. Content and Manner Exception
7. Fees Exception
8. Licensing Exception

Setting the Stage for Some Real-World Examples

- Examples we discuss today are illustrative examples and are not a comprehensive catalog. Many other types of actions or omissions (“practices”) could also implicate the information blocking provision.
- A determination as to whether a “practice” would be information blocking requires a fact-based, case-by-case assessment.
- Such a case-by-case assessment considers all relevant individual facts and circumstances against **all** the elements of information blocking.
- For ease of discussion, samples focus on the likelihood of a “practice” being an “interference,” but practices likely to interfere are “information blocking” only if they meet **all** elements of information blocking.

Elements of Information Blocking
<input type="checkbox"/> Not “required by law”
<input type="checkbox"/> Not covered by an exception
<input type="checkbox"/> Likely to “interfere with” access, exchange, or use
<input type="checkbox"/> Electronic health information (EHI)
<input type="checkbox"/> By an “Actor”
<input type="checkbox"/> Requisite knowledge of “Actor”

What is to “*interfere with*,” access, exchange, or use?

- “Interfere with” or “interference” means to prevent, materially discourage, or otherwise inhibit.

Practice Examples (illustrative purposes only) If I . . .	Unlikely to be an Interference	Likely to be an Interference *
. . . have implemented a patient portal that includes the capability for patients to directly transmit or request direct transmission of their EHI to a third party, but I choose not to enable the capability.		✓
. . . have the capability to provide same-day access to EHI in the manner requested by a patient or a patient’s health care provider but choose to take several days to respond.		✓
. . . have implemented a FHIR API that supports patients’ access to their EHI via app but refuse to allow publication of the “FHIR service base URL” (sometimes also referenced as “FHIR endpoint”).		✓

Start to learn more:
Practices that May Implicate Information Blocking in the final rule

and

Examples of Practices Likely to Interfere in the proposed rule

* “Practices” will be evaluated on a case-by-case basis to determine whether information blocking has occurred. A practice likely to be an interference may not be information blocking if the actor’s practice is required by law, satisfies the conditions of an exception, or is done without the knowledge required on the part of the actor by the information blocking definition.

Real World Examples & Likelihood of Interference

Practice Examples (illustrative purposes only) If I . . .	Unlikely to be an Interference	Likely to be an Interference *	Start to Learn More
. . . establish an organizational policy to delay the release of all lab results until the ordering clinician reviews the results for potential risk of harm associated with release.		✓	IB.FAQ22.1.2021MAR IB.FAQ25.1.2021JAN IB.FAQ33.1.2021JAN
. . . direct my EHR developer to configure the technology so that users cannot easily send referrals/EHI to unaffiliated providers whose Direct address the user has.		✓	Rule discussion under heading: Practices Likely to Interfere
. . . educate patients about the privacy and security risks posed by third-party apps with information that is factually accurate, unbiased, objective, fair and not deceptive, in a non-discriminatory manner.	✓		IB.FAQ27.1.2020NOV
. . . choose to provide access, exchange, or use of only those Clinical Notes authored by a physician regardless of what a patient or another provider seeks.		✓	IB.FAQ15.1.2021JAN

* “Practices” will be evaluated on a case-by-case basis to determine whether information blocking has occurred. A practice likely to be an interference may not be information blocking if the actor’s practice is required by law, satisfies the conditions of an exception, or is done without the knowledge required on the part of the actor by the information blocking definition.

Information Blocking Regulations & HIPAA Business Associate Agreements

- Under the HIPAA Privacy Rule, a BAA (business associate agreement) must contain certain elements, including a description of the permitted and required uses of PHI (protected health information) by the BA, who will not use or further disclose the PHI other than as permitted or required (by the contract or by law).
- The information blocking regulation does not require an “actor” to violate these agreements; however, the agreements must not be used in a discriminatory manner to forbid or limit disclosures that otherwise would be permitted by the Privacy Rule.

Practice Examples (illustrative purposes only)	Unlikely to be an Interference	Likely to be an Interference *
If I . . .		
. . . enter into a BAA that prohibits or limits the access, exchange, or use of the EHI by other health care providers treating the patient.		✓
. . . use a BAA in a discriminatory manner to forbid or limit disclosures that otherwise would be permitted by the Privacy Rule.		✓

Start to learn more:
IB.FAQ28.2.2021APR

* “Practices” will be evaluated on a case-by-case basis to determine whether information blocking has occurred. A practice likely to be an interference may not be information blocking if the actor’s practice is required by law, satisfies the conditions of an exception, or is done without the knowledge required on the part of the actor by the information blocking definition.

Real World Examples: How Much EHI, and How to Share EHI?

Practice Examples (illustrative purposes only)	Start to Learn More
If I tailor the amount of EHI that I share to what is sought, without artificially restricting or otherwise influencing the scope of EHI sought?	IB.FAQ21.1.2020NOV
. . . charge an individual, their personal representative, or another person or entity designated by the individual for <i>electronic access</i> to the individual's EHI?	ONC Cures Act Rule
... lack the technical capability to segment data the patient has refused consent to disclose from other EHI that I could permissibly disclose to another provider for treatment purposes?	ONC Cures Act Rule

Note: “Actors” have significant discretion and flexibility in determining how best to document exceptions.

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Information Sharing: Things to Consider

- Review your policies and processes –
 - Are they optimized for you, your staff, and your patients to access, exchange, and use EHI whenever it is legally permissible?
- Review your technology –
 - Are you making the most of its capabilities for facilitating information access, exchange, and use?
- Engage your colleagues and patients –
 - Are you talking to your developer about enhancing the capabilities?
 - Are you empowering clinical and non-clinical staff to help patients understand when and how they can choose to access their EHI?
 - Has your organization informed your patients what EHI is available to them in their portal and how to get EHI they want that's not in the portal?

Penalties & Enforcement

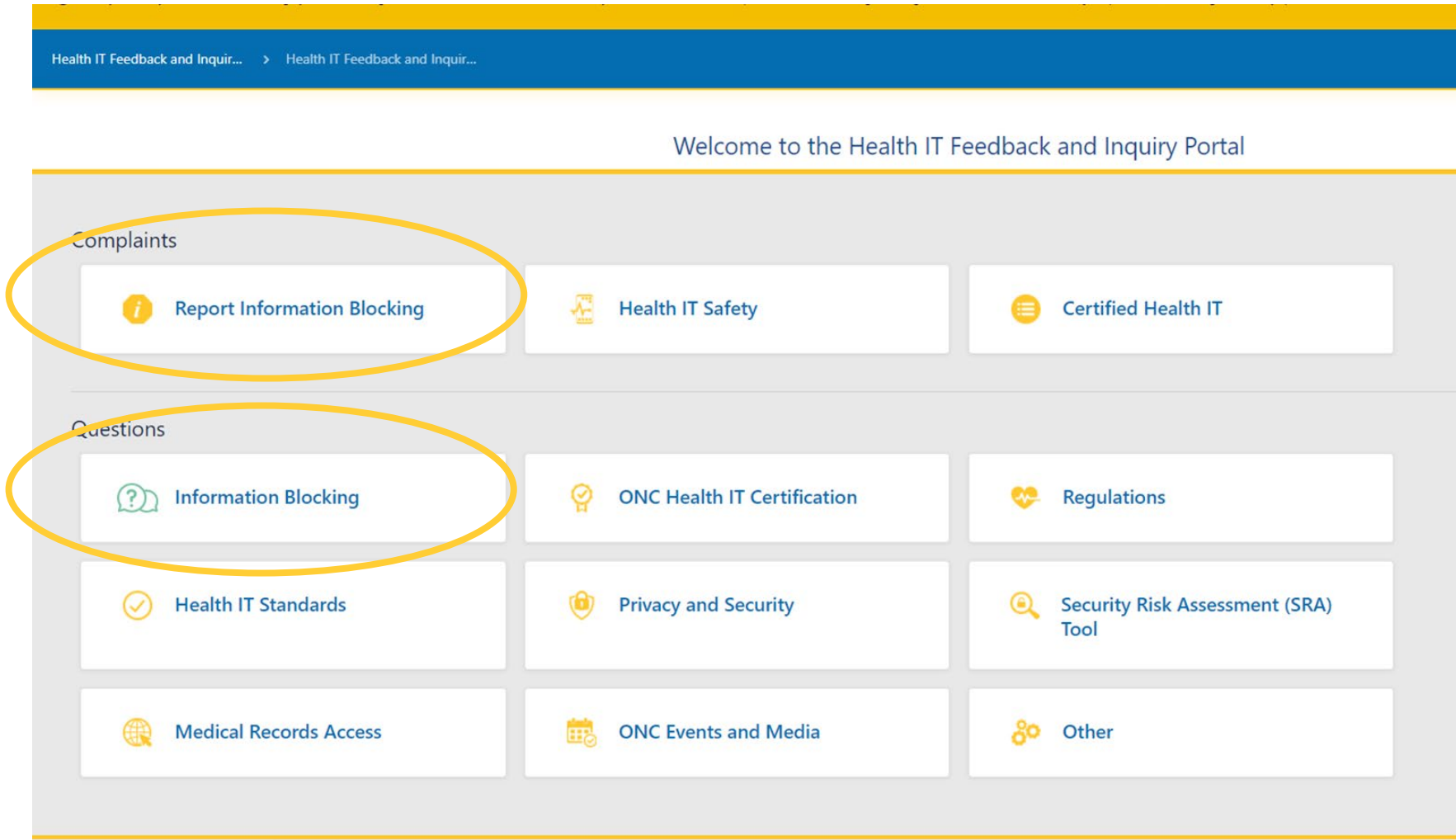
“Actor”	Penalty
Health care providers	<ul style="list-style-type: none"> • Appropriate disincentives to be established in regulations
Health information networks and Health information exchanges	<ul style="list-style-type: none"> • Civil monetary penalties (CMPs) up to \$1 million per violation
Health IT developers of certified health IT	<ul style="list-style-type: none"> • Civil monetary penalties (CMPs) up to \$1 million per violation • Certification ban for violation of the Conditions of Certification • Public listing of certification bans and terminations

TIMING: Enforcement of information blocking civil monetary penalties (CMPs) will not begin until established by OIG final rule. This final rule is expected later this year (2021).

For health care providers, appropriate disincentives will need to be established in future HHS rulemaking.

Where to Ask a Question or Report a Concern?

www.HealthIT.gov/feedback



Health IT Feedback and Inquir... > Health IT Feedback and Inquir...

Welcome to the Health IT Feedback and Inquiry Portal

Complaints

- Report Information Blocking
- Health IT Safety
- Certified Health IT

Questions

- Information Blocking
- Health IT Standards
- Medical Records Access
- ONC Health IT Certification
- Privacy and Security
- ONC Events and Media
- Regulations
- Security Risk Assessment (SRA) Tool
- Other

The screenshot shows the Health IT Feedback and Inquiry Portal. The page is titled "Welcome to the Health IT Feedback and Inquiry Portal". It is divided into two main sections: "Complaints" and "Questions". Under "Complaints", there are three buttons: "Report Information Blocking", "Health IT Safety", and "Certified Health IT". Under "Questions", there are nine buttons arranged in a 3x3 grid: "Information Blocking", "Health IT Standards", "Medical Records Access", "ONC Health IT Certification", "Privacy and Security", "ONC Events and Media", "Regulations", "Security Risk Assessment (SRA) Tool", and "Other". The "Report Information Blocking" button under "Complaints" and the "Information Blocking" button under "Questions" are circled in yellow.

Contact ONC about Information Blocking:

Health IT Feedback & Inquiry Portal
(healthit.gov/feedback)

Contact ONC about other topics through the
Health IT Feedback & Inquiry Portal or visit
healthit.gov/topic/contact-us for more options

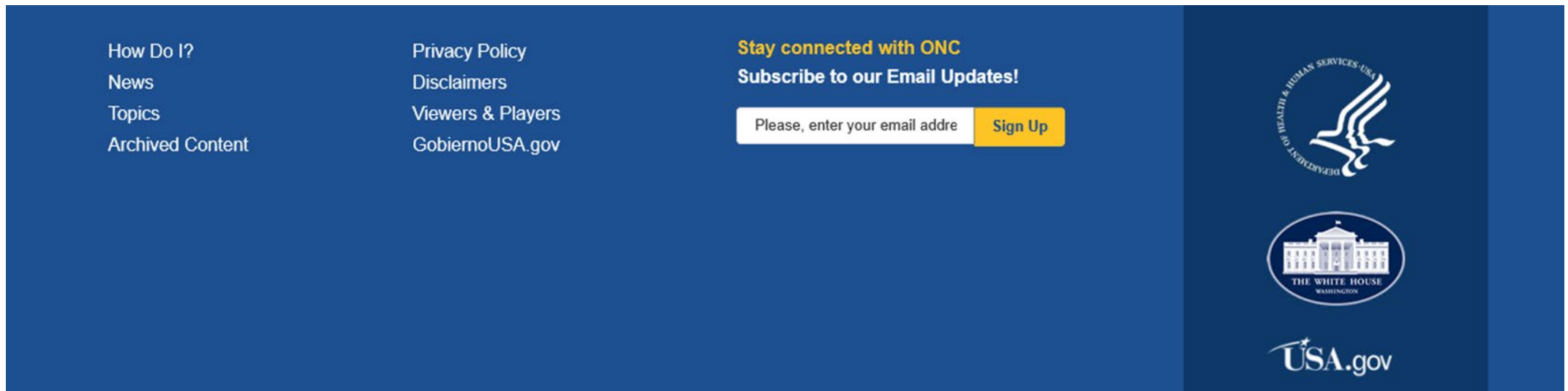
For the latest updates,
[subscribe](#) to our weekly
eblast at:



Reminder

- For information on upcoming webinars and events, subscribe to ONC email updates.
- Upcoming webinar: ***Ask Us About Information Sharing*** on September 24

www.healthit.gov





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Where To Find More Information

ONC Website Resources: www.HealthIT.gov/CuresRule

Factsheets: <https://www.healthit.gov/curesrule/resources/fact-sheets>

FAQs: <https://www.healthit.gov/curesrule/resources/information-blocking-fa>

Blogs: <https://www.healthit.gov/buzz-blog/category/21st-century-cures-act>



ONC's Cures Act Final Rule

HealthIT.gov | Email Updates | View Final Rules

Overview ▾ What It Means for Me ▾ Final Rule Policy ▾ Resources ▾

Resources ▾

- Fact Sheets
- Webinars
- Media/Press
- Blog Posts
- View Final Rules
- Information Blocking FAQs

21st Century Cures Act:
Interoperability, Information Blocking, and the ONC Health IT Certification Program

[Learn More](#)

Latest Updates

Extension of Compliance Dates and Timeframes in Response to COVID-19
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New Information Blocking FAQs Available
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Home > Resources > Webinars

Webinars

- Media/Press
- Blog Posts
- View Final Rules
- Information Blocking FAQs

Past Webinars

Information Blocking FAQ

Thursday, February 4, 2021 at 3 PM ET

[View Recorded Webinar](#)

Information Blocking Q&A

Wednesday, April 8, 2020 at 3 PM ET

[View Recorded Webinar](#)

[Webinar Slides \[PDF - 1.12MB\]](#)

Information Blocking

Monday, March 16, 2020 at 3:00 PM ET

[View Recorded Webinar](#)

[Webinar Slides \[PDF - 1.9MB\]](#)

ONC's Cures Act Final Rule Overview Webinar

Wednesday, March 11, 2020 at 3:00 PM ET

[View Recorded Webinar](#)

[View Webinar Slides \[PDF - 2.88MB\]](#)