

What Clinicians and Other Health Care Providers Need to Know

How the Exceptions Empower Providers and Support Information Sharing: Part 1

November 17, 2021



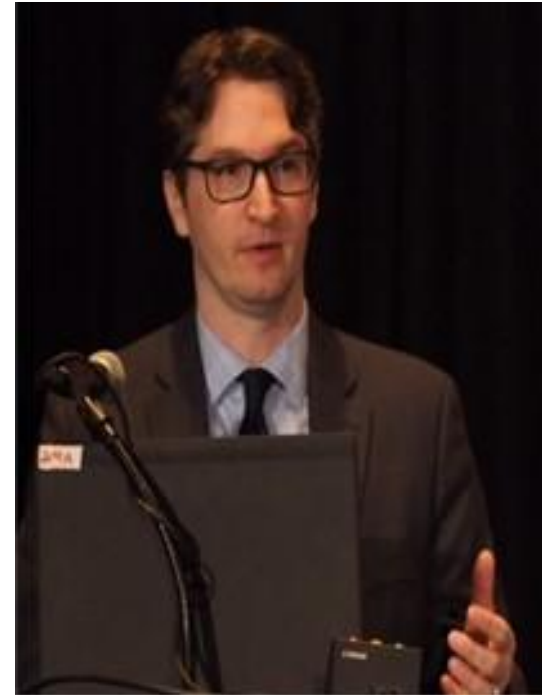
General Disclaimers

- **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.
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Speakers



Thomas Keane, MD
Clinical Officer
HHS/ONC



Michael Lipinski, JD
Director, Regulatory & Policy Affairs
Office of Policy
HHS/ONC

ONC Clinical Council

- Thomas Mason, MD Chief Medical Officer
- Kiri Bagley, MD
- Wanda Govan-Jenkins, DNP, MS, MBA, RN
- David R. Hunt, MD, FACS
- Thomas Keane, MD
- Elizabeth Palena-Hall, RN
- LaVerne M. Perlie, MSN, BSN
- Tricia Lee Rolle, PharmD
- Albert Taylor, MD

Welcome

Introductory Remarks from the National Coordinator

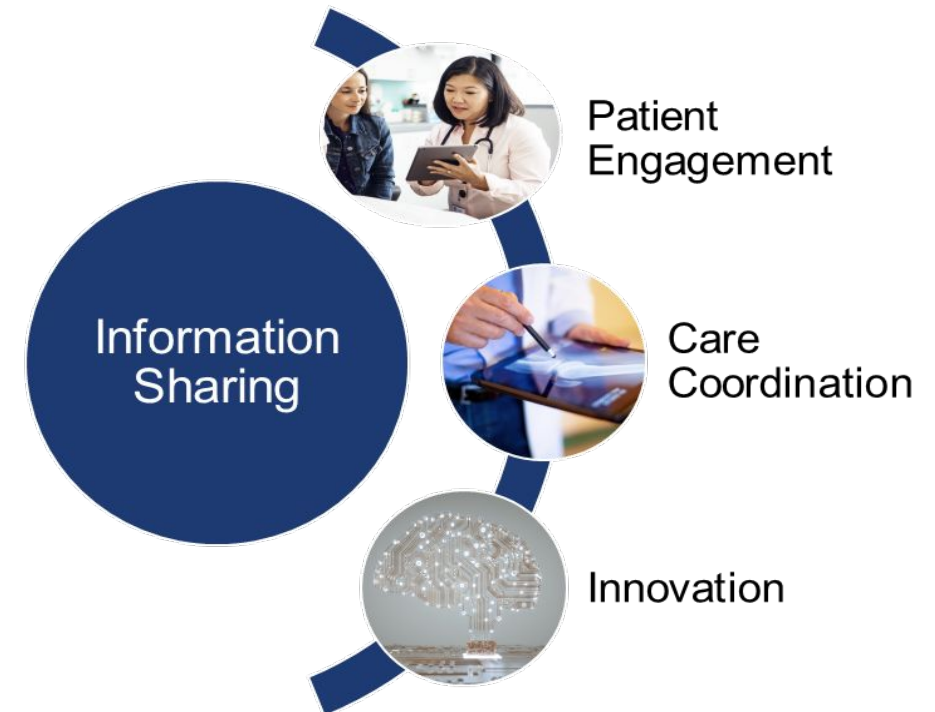
Micky Tripathi, PhD, MPP



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 HHS Office of the National Coordinator for Health IT (ONC) with **implementing 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.

Learning Objectives

- **Identify reasonable and necessary activities or “exceptions”**
- **Understand ways to utilize the exceptions**
- **Address some common misconceptions**
- **Understand why information sharing matters**
 - Supporting care coordination
 - Supporting point of care delivery
 - Supporting public health, population health, and research
- **Describe how a claim can be reported and ONC's initial processing of claims**
- **Identify where to find more information**

Exceptions: Identifying reasonable and necessary activities

Promote confidence in health IT infrastructure

- Privacy and security
- Patient safety

Promote competition and innovation

- Usability and modernization of technology
- Greater value, more choices, reduced burden

Promote standardization and interoperability

- Greater accessibility, including for research
- Better quality and equitable health outcomes

Exceptions Policy

1. Identify certain **reasonable and necessary activities** that do not constitute information blocking
2. Address practices of **significant risk** for actors not engaging in them due to uncertainty about the information blocking regulations
3. Through appropriate conditions, **limit to protect and not extend** beyond, reasonable and necessary activities

Eight Information Blocking Exceptions



- **Information Sharing:** the norm is to avoid actions or omissions (“practices”) that are likely to interfere with information sharing.
- **Exceptions:** the exceptions offer assurance that **reasonable and necessary** “practices” covered by an exception will **not** be **considered information blocking**.

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

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

Applicable to processes or 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

- 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

Who is covered by the information blocking regulations?

Health IT Developers of Certified Health IT

Health Information Networks & Health Information Exchanges

Health Care Providers

Information Blocking Exceptions

- **Satisfying the conditions and documenting use of an exception:**
 - Failure to meet an exception does not mean that an actor's practice meets the information blocking definition.
 - The actor's documented record should reflect what would be needed to demonstrate the actor met each of the conditions or requirements of the exception.

Limiting the content or manner when fulfilling a request

Frequently Asked Question (FAQ):

- Is portable document format (PDF) considered a “machine-readable format” for purposes of the alternative manner condition of the content and manner exception? (NEW FAQ)
- **Alternative Manner**
 - Order of priority
 - Agreed to by the requestor
 - Without unnecessary delay

*

“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.

Content and Manner Exception

- Actor must meet **BOTH** conditions:
 1. **Content condition**
 - Before October 6, 2022, EHI identified by the data elements represented in USCDI v1 standard.
 - On and after October 6, 2022, EHI without the limitation.
- AND**
2. **Manner condition**
 - Any manner unless: (1) technically unable to fulfill in the manner requested; or (2) cannot reach agreeable terms with the requestor



Not fulfilling a request due to infeasibility

Questions:

- What if a patient requests EHI in an electronic form, and I don't have an EHR?
- What if the parents of an adolescent request information related to the adolescent patient's juvenile diabetes, but release would reveal that the patient has been prescribed OCPs, information that the patient has requested not be revealed to her parents. There is no way to electronically segment the OCP Rx from the other information.

NOTE: In this scenario, the adolescent has reached the state's age of consent – ability to block any data from the parent.

- **One of Three Conditions** - It will not be information blocking if an actor does not fulfill a request to access, exchange, or use EHI due to the infeasibility of the request, provided certain conditions are met.
 - **Uncontrollable Events:** Must be **due to** events beyond the actor's control.
 - **Segmentation:** Cannot unambiguously segment the requested EHI from other EHI.

*

“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.

Infeasibility Exception

- **Actor must demonstrate that the practice meets 1 of 3 conditions for:**
 1. **uncontrollable events**
 2. **segmentation, OR**
 3. **infeasibility under the circumstances**
- **Must provide written response within 10 business days of request with the reason(s) why it is infeasible**



Charging fees, including fees that result in a reasonable profit margin

Frequently Asked Question (FAQ):

- If an individual asks an actor to provide a copy of the individual's electronic health information (EHI) in some form of physical media, such as where the EHI is printed to paper or copied onto a CD or USB drive, could the individual's request implicate the information blocking regulations and may any fees be charged? (NEW: IB.FAQ38.1.2021NOV)

- **Not Covered** - The exception would not apply to an actor that charges individuals a fee in order for the individuals to receive access to their EHI using an internet-based delivery method, including where an individual uses consumer-directed technology (e.g., patient chosen apps, personal health apps, standalone/untethered personal health records (PHR), email) to request and/or receive their EHI.
- This includes sharing it with an entity designated by the individual (e.g., allowing individuals to donate/share EHI with a biomedical research program of the individual's choice).

* "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.

Fees Exception

- Practice must meet basis for fees condition
 - Not be specifically excluded
 - Comply with Conditions of Certification at
 - § 170.402(a)(4) (Assurances)
- OR
- § 170.404 (API)



Licensing

Questions: Am I required to provide EHI if . . .

- My radiology practice subscribes to a web-based PACS system and would like to offer a seat license to any referring physician requesting PACS access. Can we charge the referring physician for the cost of the license?
- I've built a mobile app that works by interfacing with an EHR. The EHR vendor is requiring me to license the source code for the application if I want the app to interface with their product. Can they do this?
- **Interoperability Element** - means hardware, software, integrated technologies or related licenses, technical information, privileges, rights, intellectual property, upgrades, or services that: (1) may be necessary to access, exchange, or use EHI; and (2) is controlled by the actor, which includes the ability to confer all rights and authorizations necessary to use the element to enable the access, exchange, or use of EHI.
- **Contract Terms** - a contract may implicate the information blocking provision if it included unconscionable terms for the access, exchange, or use of EHI or licensing of an interoperability element, which could include, but not be limited to, requiring a software company that produced a patient access application to relinquish all IP rights to the actor or agreeing to indemnify the actor for acts beyond standard practice, such as gross negligence on part of the actor.

* “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.

Licensing Exception

- Practice must meet the negotiating a license conditions
- Practice must meet the licensing conditions
- Practice must meet the additional conditions relating to the provision of interoperability elements
- Reasonable royalty permitted



What is Electronic Health Information (EHI)?

Frequently Asked Questions (FAQ):

- For the period of time when information blocking is limited to the United States Core Data for Interoperability, what constitutes a progress note for the purposes of information blocking? (NEW: B.FAQ40.1.2021NOV)
- When information blocking is no longer limited to the subset that is represented by data elements in the United States Core Data for Interoperability (USCDI), what information will be covered by information blocking regulations as “electronic health information (EHI)”?
IB.FAQ39.1.2021NOV

Data Elements Represented in USCDI v1

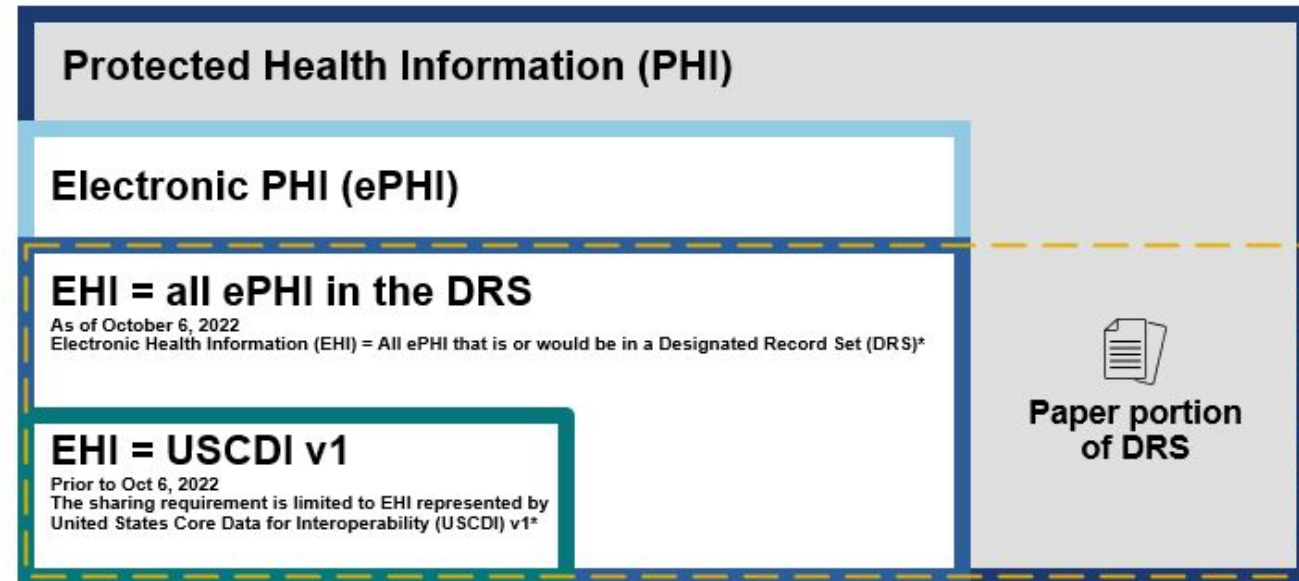
Allergies and Intolerances <ul style="list-style-type: none"> Substance (Medication) Substance (Drug Class) Reaction 	Clinical Notes <ul style="list-style-type: none"> Consultation Note Discharge Summary Note History & Physical Imaging Narrative Laboratory Narrative Report Pathology Report Narrative Procedure Note Progress Note 	Patient Demographics <ul style="list-style-type: none"> 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 	Smoking Status
Assessment and Plan Of Treatment	Goals <ul style="list-style-type: none"> Patient Goals 	Problems	Unique Device Identifier(s) for a Patient's Implantable Device(s)
Care Team Members	Health Concerns	Procedures	Vital Signs <ul style="list-style-type: none"> 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)
 <p>For more info: HealthIT.gov/USCDI</p>	Immunizations	Provenance <ul style="list-style-type: none"> Author Time Stamp Author Organization 	
	Laboratory <ul style="list-style-type: none"> Tests Values/Results 		
	Medications		

United States Core Data for Interoperability (USCDI)

- * “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.

What is Electronic Health Information (EHI)?

- With limited exceptions, the HIPAA Privacy Rule gives individuals the right to access, upon request, the medical and health information (**protected health information or PHI**) about them in one or more **designated record sets** maintained by or for the individuals' health care providers and health plans (HIPAA covered entities). See *45 CFR 164.524*.
- **Designated record sets** include medical records, billing records, payment and claims records, health plan enrollment records, case management records, as well as other records used, in whole or in part, to make decisions about individuals. See *45 CFR 164.501*.
- Electronic Health Information (EHI) is **electronic protected health information (ePHI)** that would be included in a **designated record set**, as these terms are defined for HIPAA, regardless of whether the “actor” the data is held by or for is a HIPAA covered entity or not.



— — Designated Record Set (DRS) Scope

Note: Diagram is not proportioned to scale.

* EHI does not include psychotherapy notes as defined in 45 CFR 164.501 or information compiled in reasonable anticipation of, or for use in, a civil, criminal, or administrative action or proceeding.

Note: PHI includes individually identifiable health information (IIHI) both in and outside of a DRS.

Note: United States Core Data for Interoperability (USCDI) describes what EHI is within the scope based on the dates specified in the regulation. From **April 5, 2021 through October 5, 2022**, EHI for information blocking purposes is limited to EHI identified by the data elements represented in the USCDI v1. **On and after October 6, 2022**, EHI for information blocking purposes is no longer limited to EHI identified by the data elements represented in the USCDI v1.

A Few Misconceptions

Frequently Asked Questions (FAQ):

- Is a claim of information blocking predicated on a request for access, exchange, or use of electronic health information (EHI)? In other words, does someone always have to ask an actor for EHI before the actor's practice could violate the information blocking definition? (NEW: IB.FAQ37.1.2021NOV)
- Do the information blocking regulations (45 CFR Part 171) require actors to proactively make electronic health information (EHI) available through "patient portals," application programming interfaces (API), or other health information technology for patients? (Revised from January 2021 NEW: IB.FAQ23.2.2021NOV)

ONC's Cures Act Final Rule and Supporting Information Sharing

- Facilitates seamless and secure access, exchange, and use of electronic health information.
- Facilitates appropriate sharing of electronic health information.
- Promotes innovation and opportunities to provide consumers and providers new products and services.
- Creates richer information exchange for more affordable, equitable, and higher quality care.

Sharing Information

- **Supports Patient Engagement and Point of Care Delivery**
 - Patient Access
 - Quality of Care, Patient Safety, and Patient Outcomes
 - Cost and Time Savings – Filling Requests and Patient Satisfaction
- **Supports Care Coordination**
 - Clinician and Health Care Provider Access – Care Team
 - Quality of Care, Patient Safety, and Patient Outcomes
 - Cost and Time Savings – Duplication and Health System
- **Supports Public Health, Population Health, and Research**
 - Public Health and Social Service Benefits
 - Drug Prescribing and Dispensing
 - Public Health Agency and Federal Program Reporting
 - Research Community Access

ONC's Cures Act Final Rule and Supporting Information Sharing

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- Promotes innovation and opportunities to provide consumers and providers new products and services.
- Creates richer information exchange for more affordable, equitable, and higher quality care.

How to Ask a Question or Report Information Blocking?

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



ONC Health IT Certification



Regulations



Health IT Standards



Privacy and Security



Security Risk Assessment (SRA)
Tool



Medical Records Access



ONC Events and Media



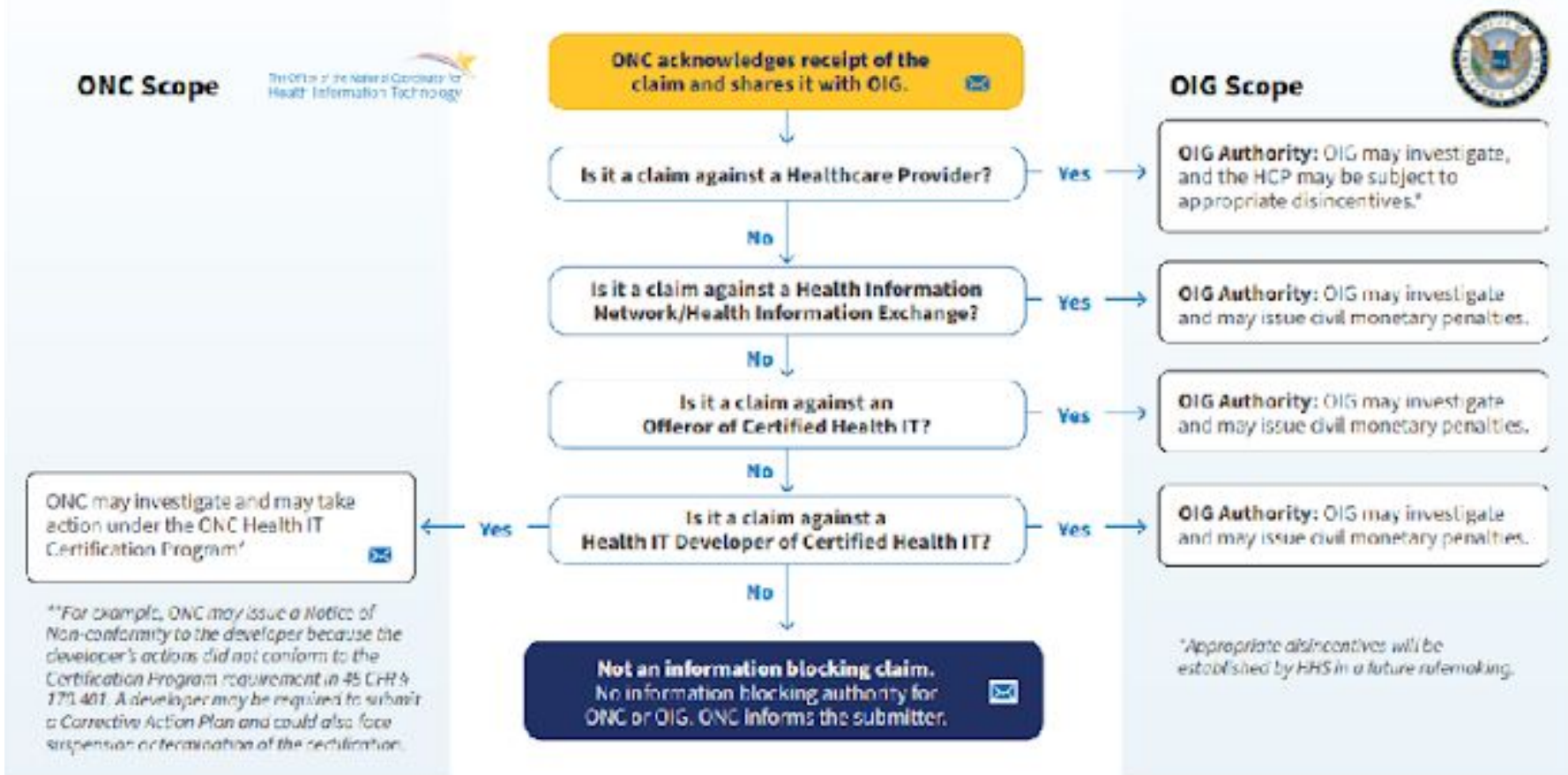
Other



What happens when a claim is submitted to the Information Blocking Portal?

This guide is for informational purposes only. The official requirements are contained in the relevant statutes and regulations.

✉ Points at which ONC communicates with submitter



ONC may investigate and may take action under the ONC Health IT Certification Program* ✉

***For example, ONC may issue a Notice of Non-conformity to the developer because the developer's actions did not conform to the Certification Program requirement in 45 CFR § 170.401. A developer may be required to submit a Corrective Action Plan and could also face suspension or termination of the certification.*

OIG Scope

- OIG Authority:** OIG may investigate, and the HCP may be subject to appropriate disincentives.*
- OIG Authority:** OIG may investigate and may issue civil monetary penalties.
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**Appropriate disincentives will be established by HHS in a future rulemaking.*

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-faqs>

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

Webinars: <https://www.healthit.gov/curesrule/resources/webinars>

The screenshot shows the top of the ONC's Cures Act Final Rule website. The navigation bar includes "Overview", "What It Means for Me", "Final Rule Policy", and "Resources". The "Resources" dropdown menu is open, listing "Fact Sheets", "Webinars", "Media/Press", "Blog Posts", "View Final Rules", and "Information Blocking FAQs". The main banner features the title "21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program" with a "Learn More" button. Below the banner, there are three sections: "Latest Updates" with a bell icon, "Extension of Compliance Dates and Timeframes in Response to COVID-19" with a "Learn More" link, and "New Information Blocking FAQs Available" with a "Learn More" link.

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 \[PDF - 2.88MB\]](#)

Reminder

- **Office Hours: Ask ONC About Information Sharing on December 10, 2021**
- For information on upcoming webinars and events, subscribe to ONC email updates at www.healthit.gov

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(healthit.gov/feedback)

Contact ONC about other topics through the
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