



# 21st Century Cures Act and a Deep Dive Into the Data Blocking Rule

Prepared for **MT HFMA & MHiMA 2022 Joint Spring Conference**  
April 29, 2022

*Presented by:*

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## **Disclaimer**

This presentation is for informational purposes only. It is not intended as medical, legal, or as a substitute for the advice of a physician, attorney, or other professional. It does not address all possible legal and other issues that may arise regarding information blocking and interoperability.

Each health care provider organization will need to consider its circumstances and requirements, which cannot be accurately contemplated or addressed in this presentation.



## Agenda

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1. Speaker Introductions
2. Information Blocking
3. Reporting
4. Timeline
5. Is it Blocking?
6. Exceptions
7. Penalties
8. Prepare: Now and Future
9. Questions

## Speaker Introduction



**Colby Terry**

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As a manager on PYA's IT Advisory services team, Colby brings broad expertise in information technology, risk management, and industry best practices to the work he performs for hospitals, clinics, behavioral health centers, health systems, the title industry, financial institutions, and managed service providers.

He has conducted a number of HIPAA Security Risk Analyses for many different types of business associates and covered entities. He has also been a member of a team conducting Graham Leach Bliley Act (GLBA) Assessments; American Land and Title Act (ALTA) Best Practices Certifications; and various IT assessments and audits to include risk management, staffing, cost/benefit analysis, infrastructure, security, and project management. Colby also leads PYA's HITRUST and SOC-2 audit services.

## Speaker Introduction



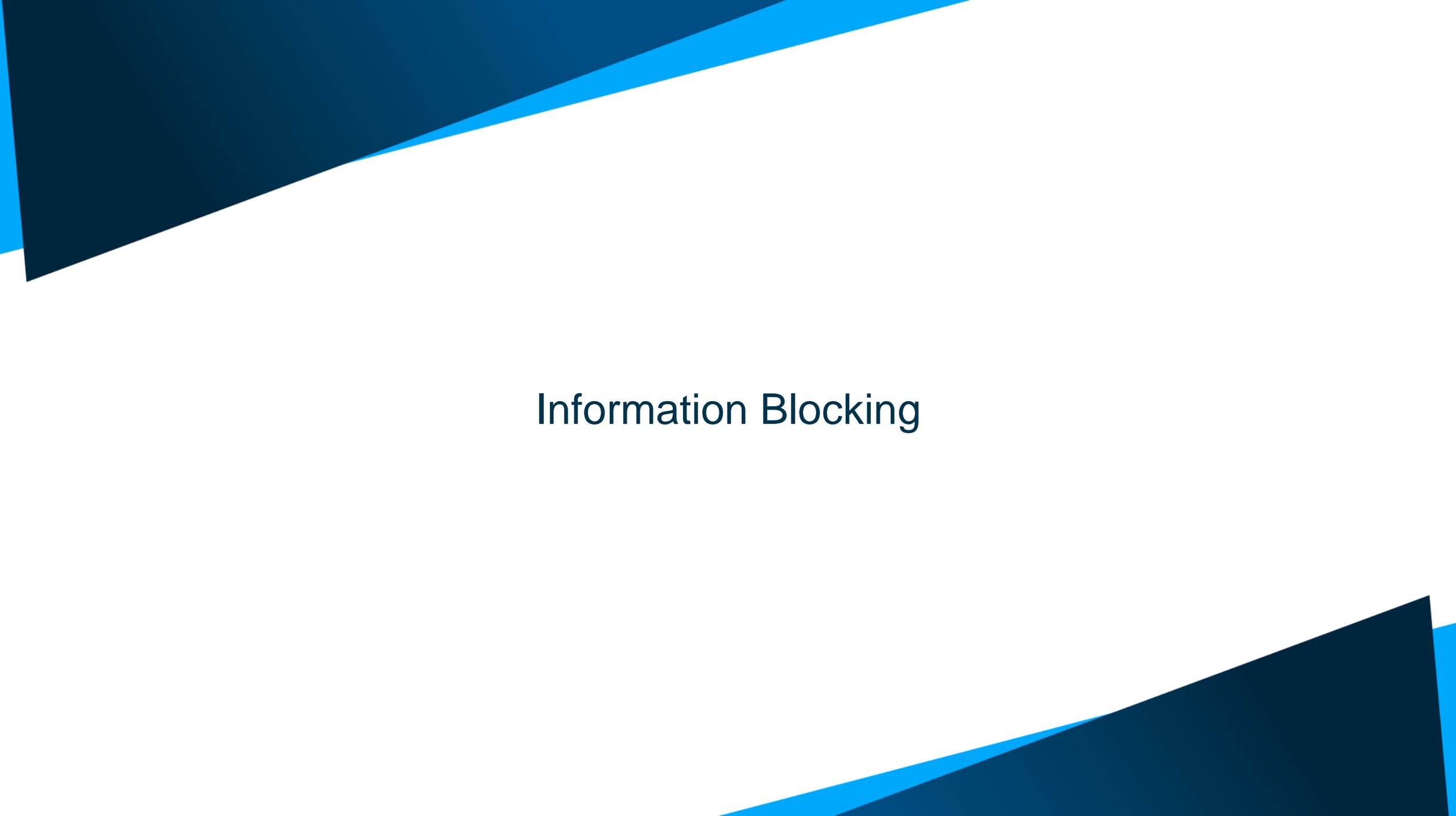
**Erin Walker**

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Erin is Certified in Healthcare Compliance, a Certified HIPAA Professional and a HITRUST Authorized CSF Assessor, specializing in HIPAA and regulatory compliance consulting matters, specifically Business Associate Agreements and HIPAA and regulatory compliance policy and procedure reviews.

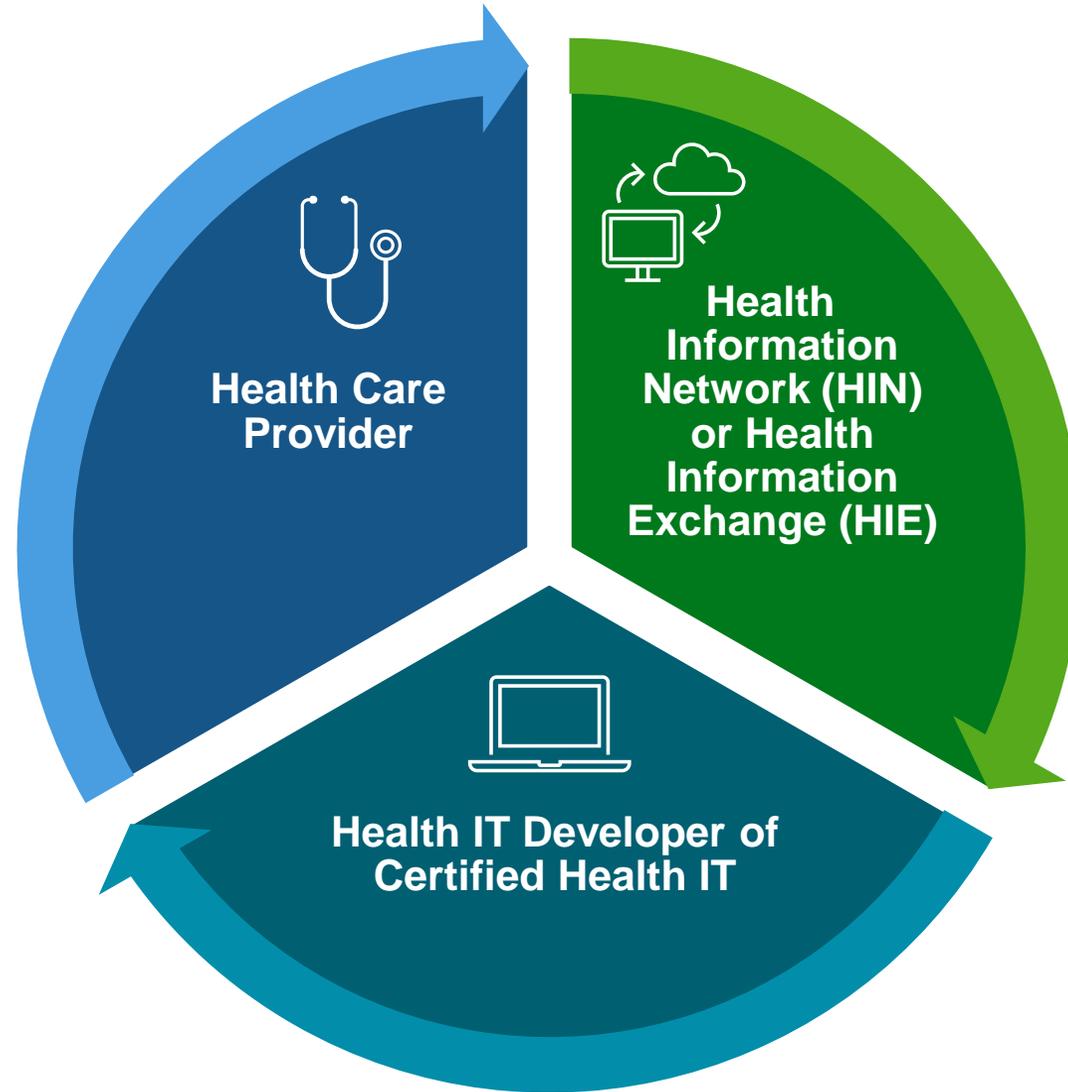
She assists with the development, documentation and implementation of policies and procedures, the compliance program and compliance risk assessment process, the HIPAA Security Risk Analysis process, and analyzes Business Associate Agreements to ensure that the satisfactory assurances required by the Privacy Rule are met.

Erin also serves as the Firm's Risk Mitigation Compliance Coordinator, assisting with risk mitigation compliance and documentation reviews on an ongoing basis.



# Information Blocking

# What Is an Actor?





Reporting

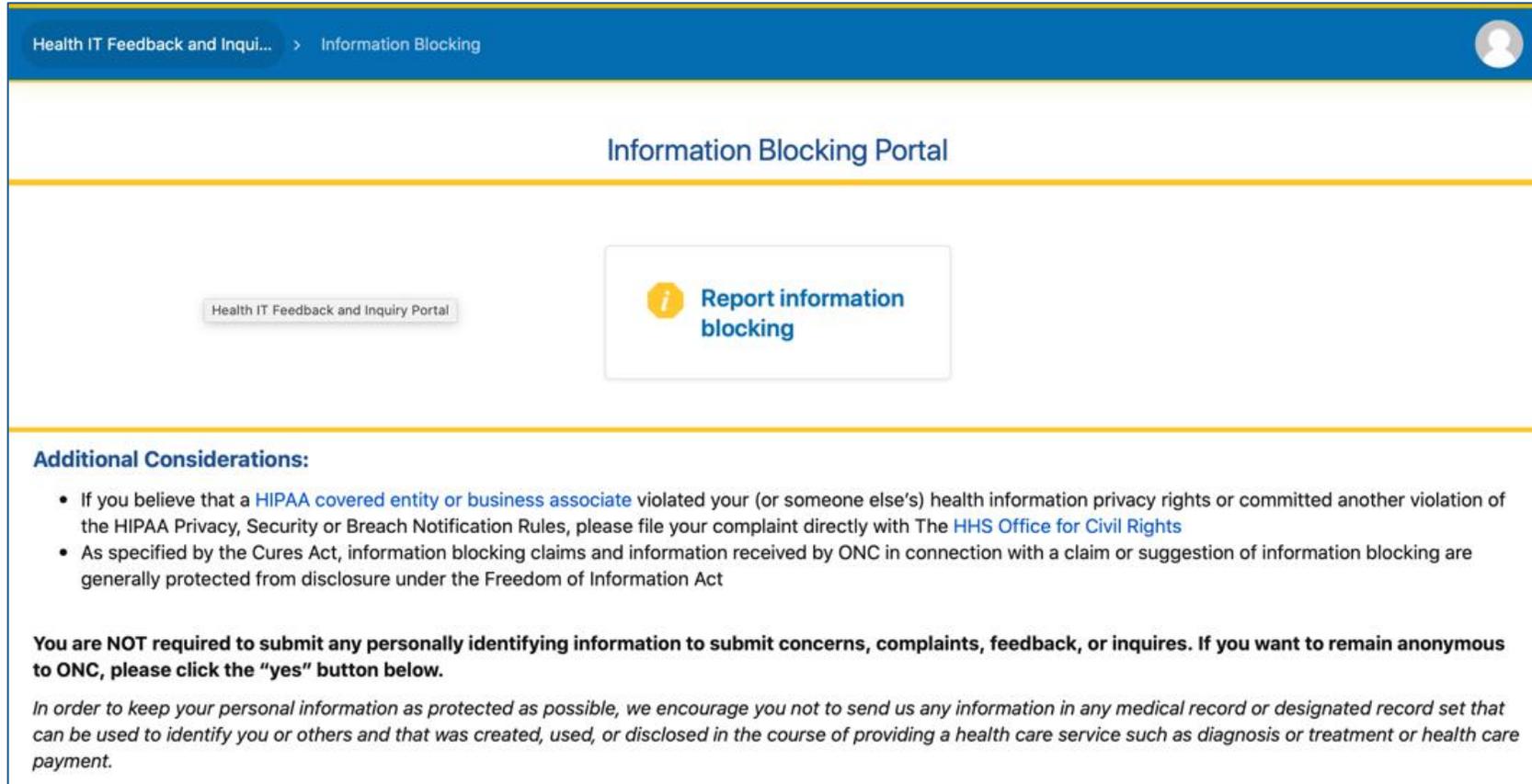


## Help Us Stop Information Blocking

The Department of Health and Human Services is working to identify and stop instances of information blocking. You can help by reporting complaints about information blocking to us via <http://www.healthIT.gov/healthITcomplaints>.

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# Information Blocking Portal



The screenshot shows a web interface for the Information Blocking Portal. At the top, there is a blue navigation bar with the text "Health IT Feedback and Inqui... > Information Blocking" and a user profile icon. Below the navigation bar, the main heading "Information Blocking Portal" is centered. A yellow horizontal line separates the header from the main content area. In the main content area, there are two buttons: a smaller one labeled "Health IT Feedback and Inquiry Portal" and a larger one labeled "Report information blocking" with an information icon. Below the buttons, there is a section titled "Additional Considerations:" followed by a bulleted list of two items. The first item states that if a HIPAA covered entity or business associate violated privacy rights, a complaint should be filed with the HHS Office for Civil Rights. The second item states that information blocking claims and information received by ONC are generally protected from disclosure under the Freedom of Information Act. Below the list, there is a bolded statement: "You are NOT required to submit any personally identifying information to submit concerns, complaints, feedback, or inquires. If you want to remain anonymous to ONC, please click the 'yes' button below." Finally, there is a paragraph of italicized text: "In order to keep your personal information as protected as possible, we encourage you not to send us any information in any medical record or designated record set that can be used to identify you or others and that was created, used, or disclosed in the course of providing a health care service such as diagnosis or treatment or health care payment."

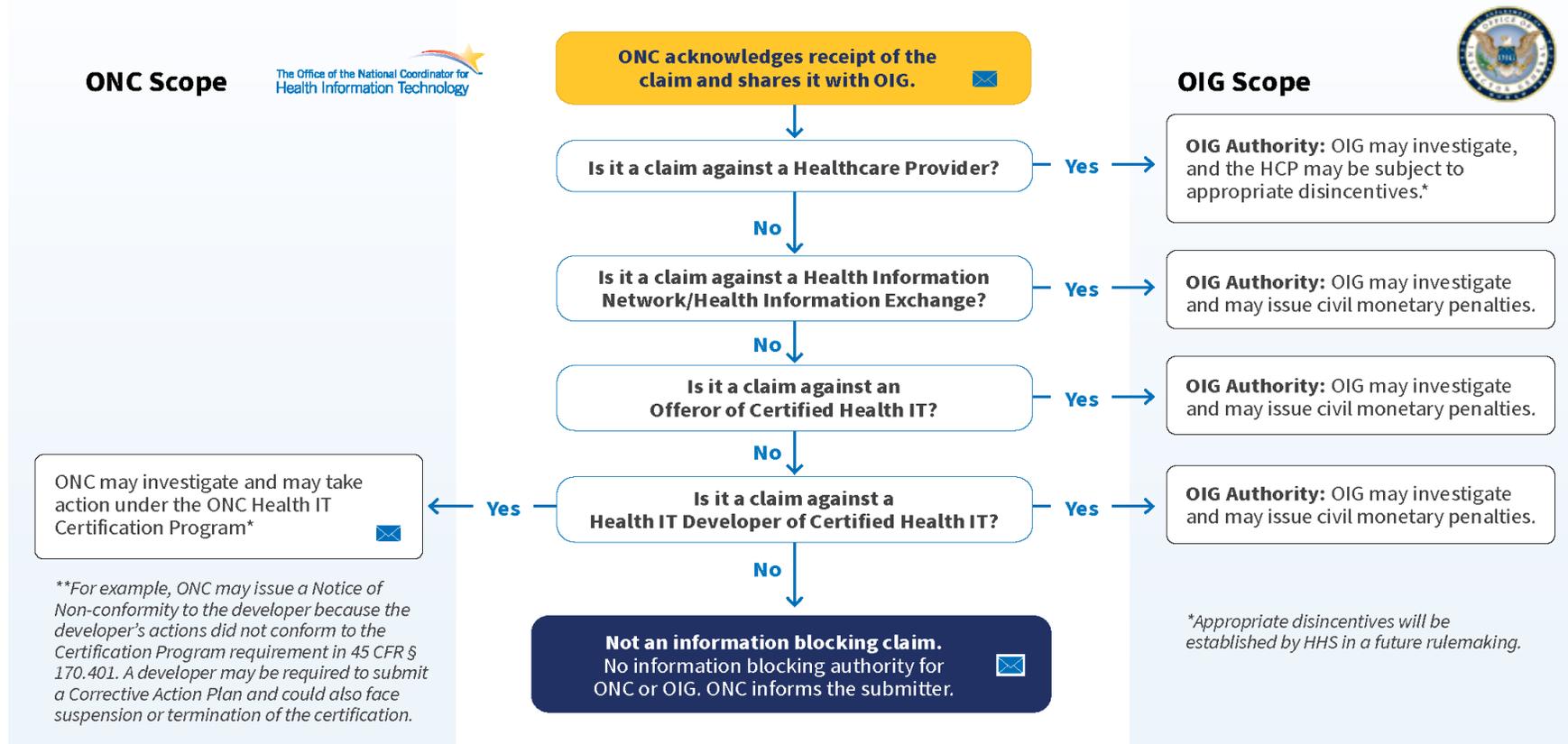
[Link to Portal](#)

# Reporting and Response



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



HealthIT.gov/CuresRule

Source: <https://www.healthit.gov/cures/sites/default/files/cures/2021-11/Information-Blocking-Portal-Process.pdf>

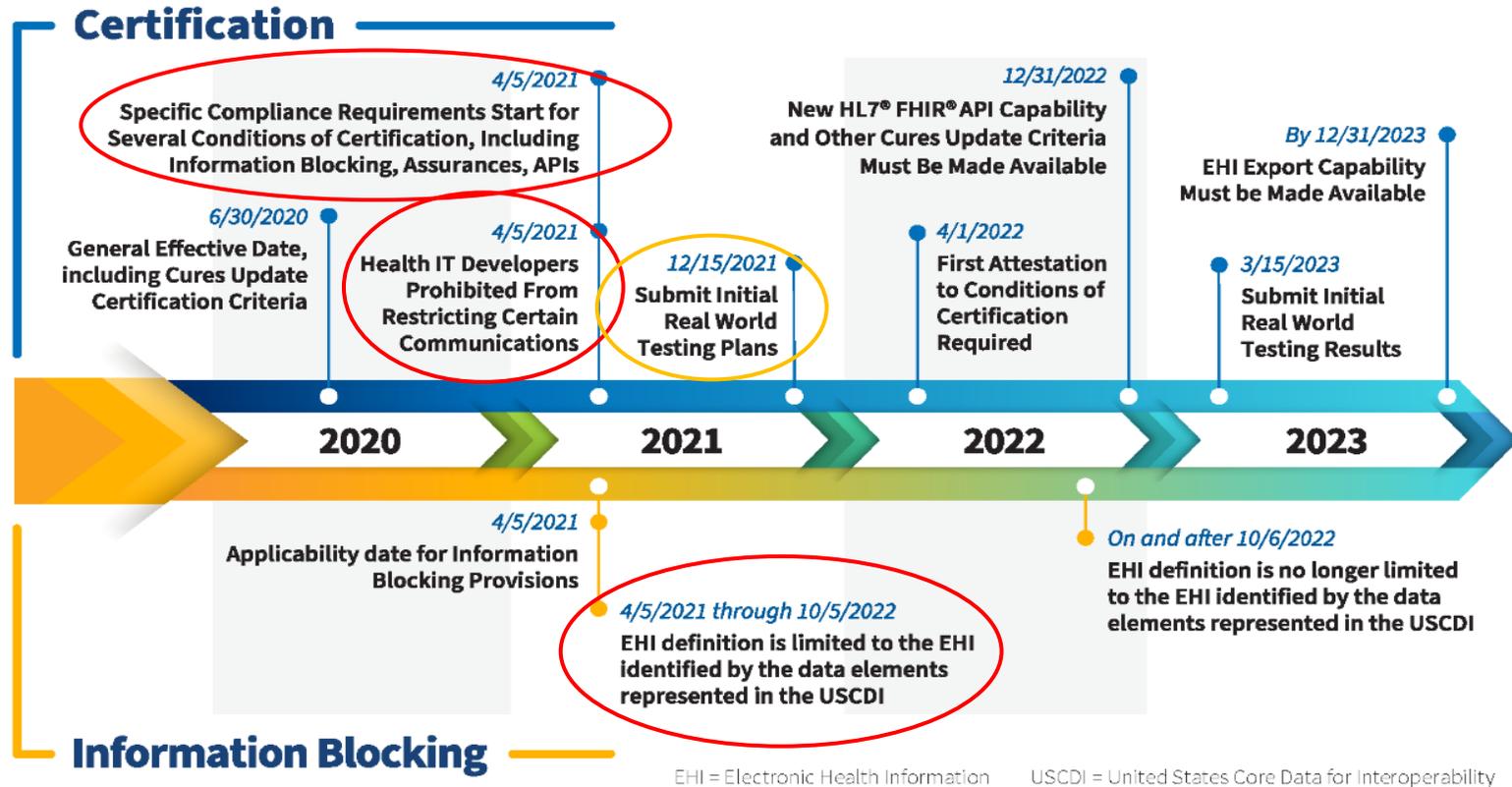
# Timeline

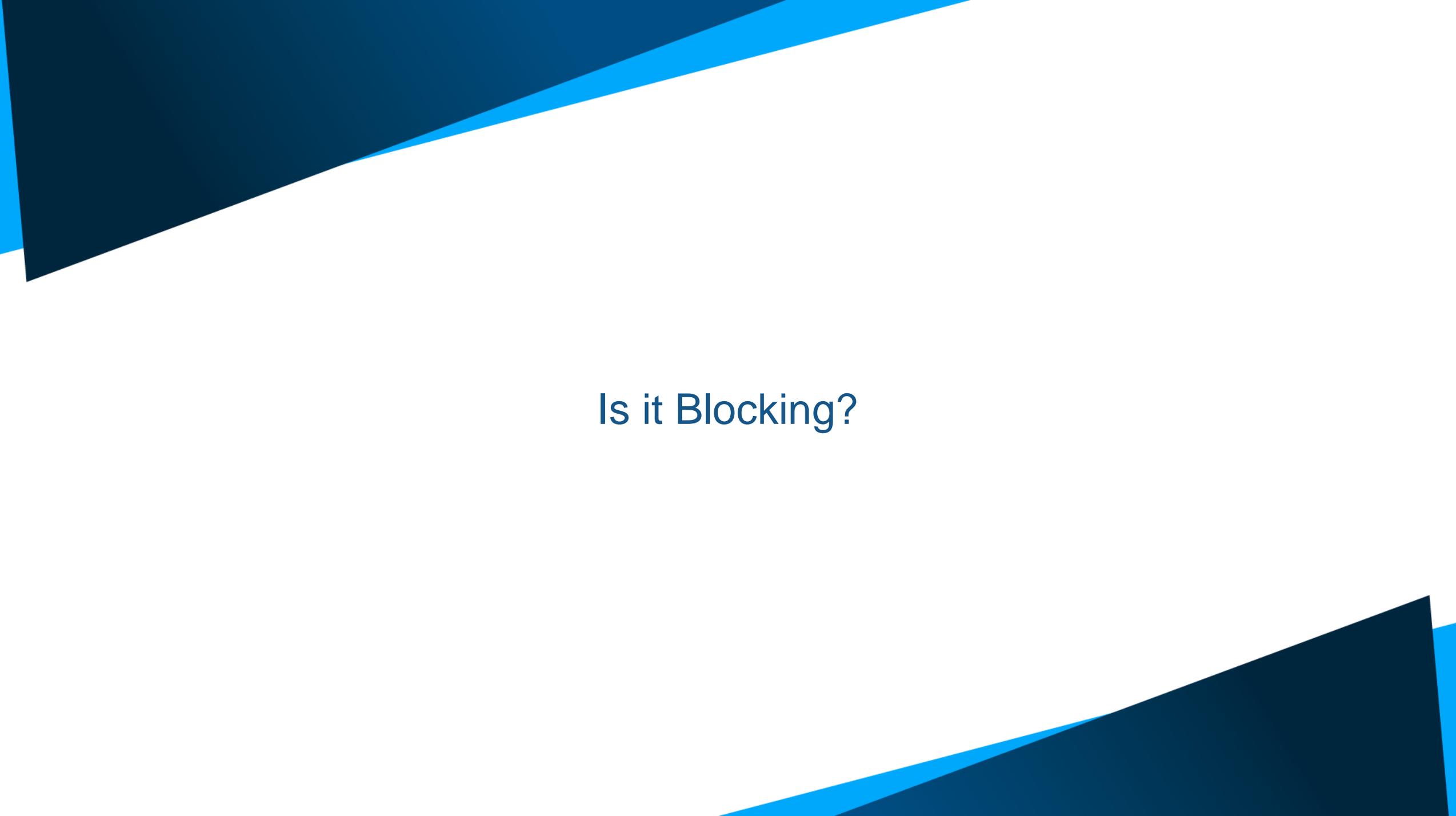
# Who Must Comply and When?



# 21st Century Cures Act – Compliance Timeline

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

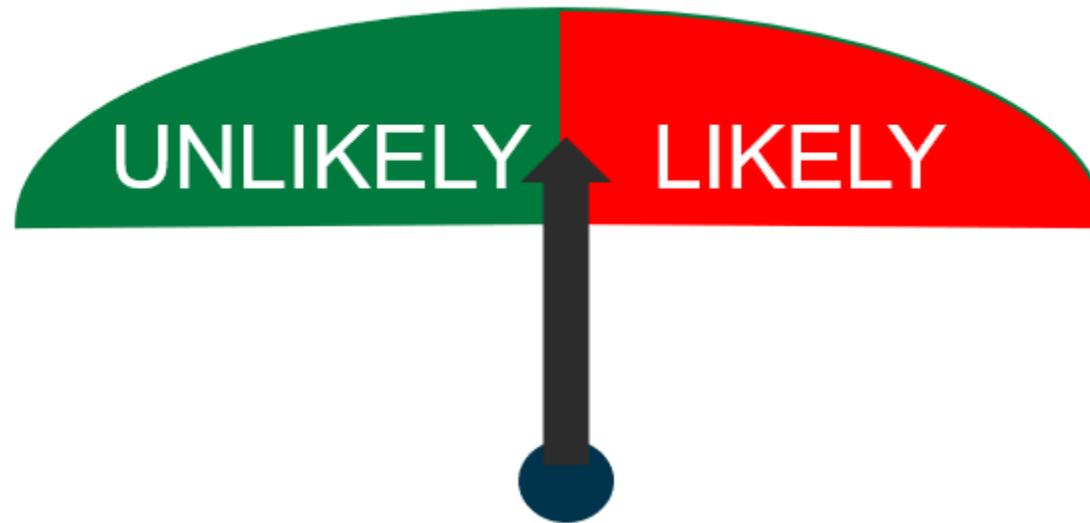




Is it Blocking?

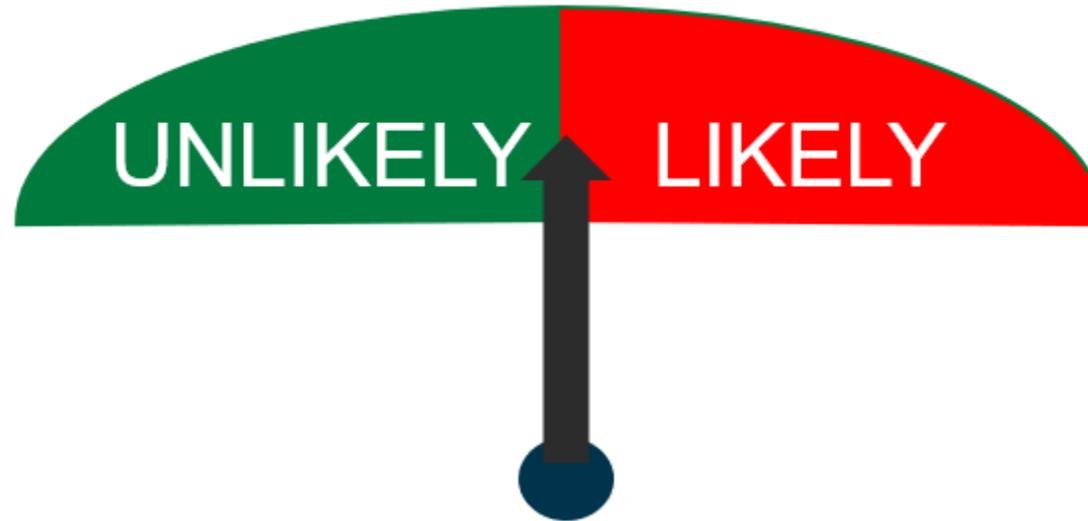
# Is it Blocking?

The release of EHI is delayed in order to ensure that the release complies with state law.



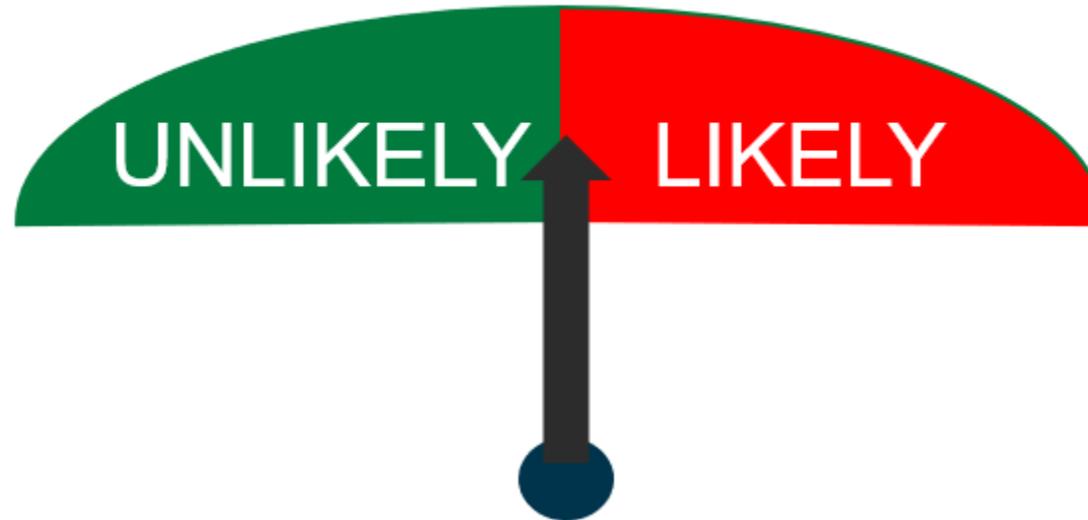
## Is it Blocking?

A health care provider established an organizational policy that, for example, imposed delays on the release of lab results in order to allow an ordering clinician to review the results, or in order to personally inform the patient of the results before a patient can electronically access such results.



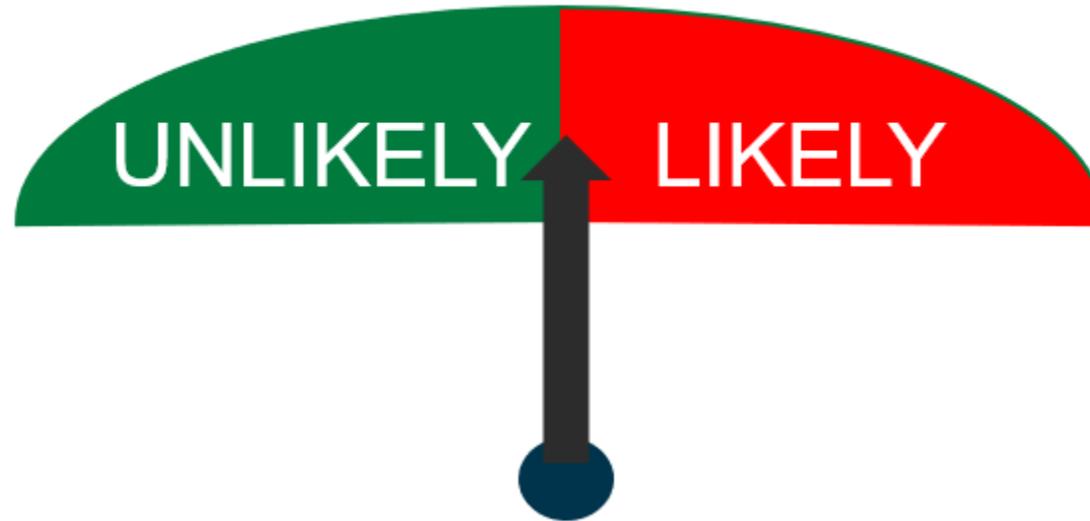
## Is it Blocking?

A delay in providing access, exchange, or use occurs after a patient logs in to a patient portal to access EHI that a health care provider has (including, for example, lab results) and such EHI is not available—for any period of time—through the portal.



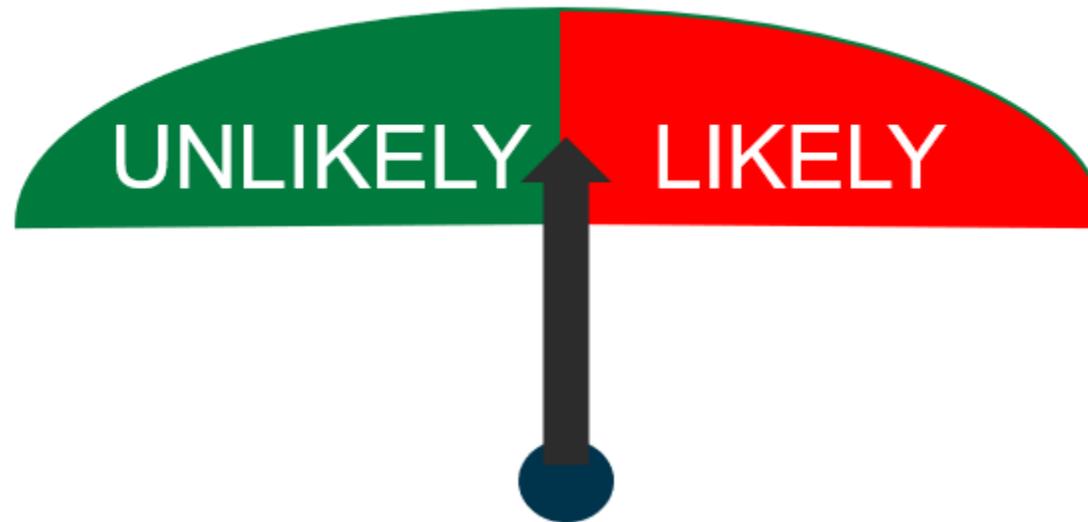
# Is it Blocking?

A delay occurs in providing a patient's EHI via an app that the patient has authorized to receive their EHI.



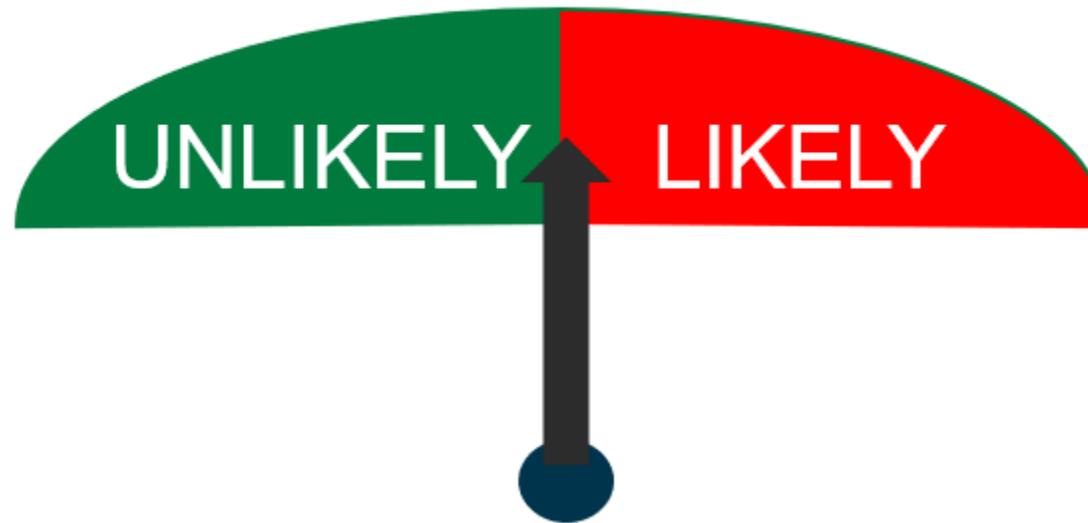
## Is it Blocking?

Two days after a patient had labs performed, she was notified her results were ready and she should schedule a call to review. The patient logged into the portal to find her results were not posted and received a message to call the office for her results.



## Is it Blocking?

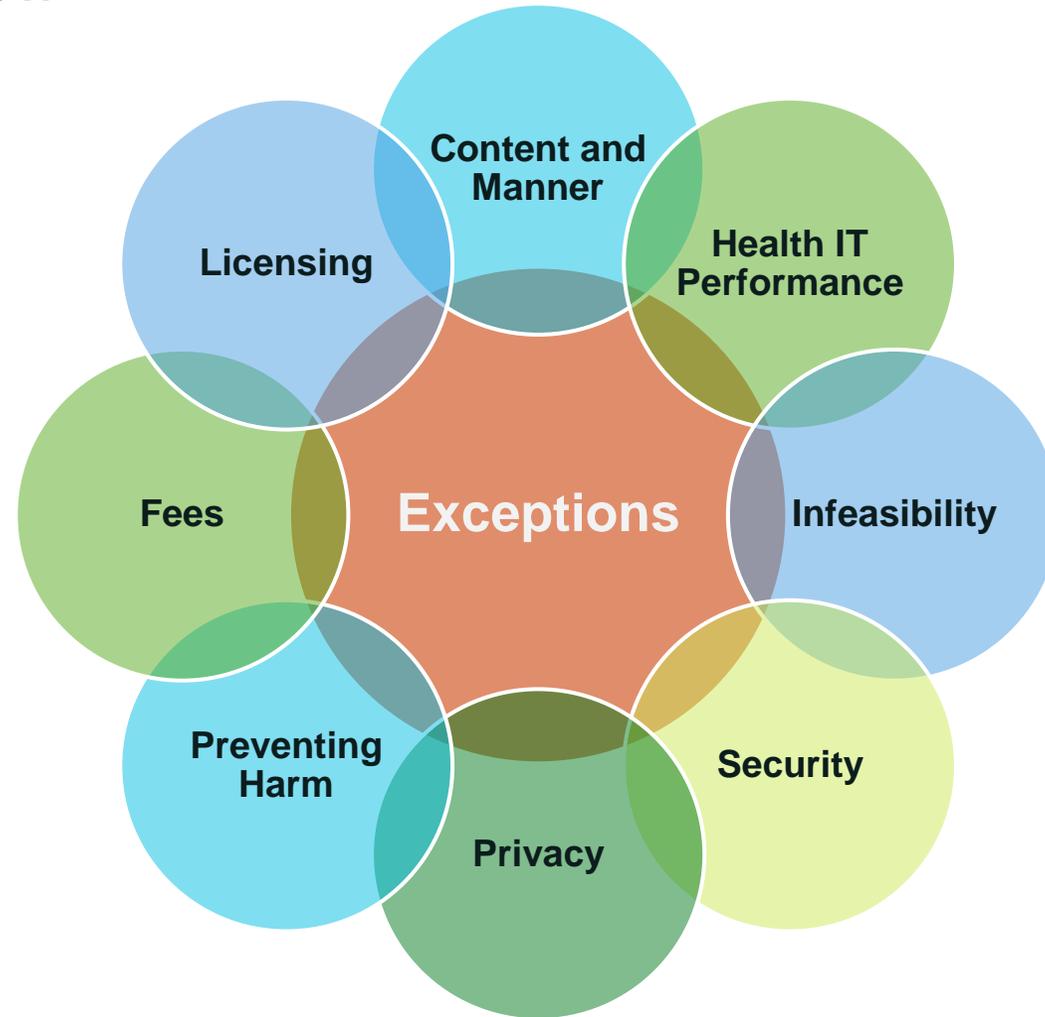
A parent requests the medical record of a child. While preparing the ROI, the actor receives a call from the estranged spouse asking the actor not to release the record. The office manager holds the record and does not release the record.





# Exceptions

# Exceptions – Overview



Source: <https://www.healthit.gov/cures/sites/default/files/cures/2020-03/ONC21stCenturyCuresActFinalRuleOverview.pdf>

## Considerations

Response must be provided in writing within 10 days of receipt of the request

Include legal in determination process

Offer alternative methods for receipt

Document, document, document

# Preventing Harm Exception

- It will not be information blocking for an actor to engage in practices that are reasonable and necessary to prevent harm to a patient or another person, provided certain conditions are met.

## Key Conditions

- The actor must hold a reasonable belief that the practice will substantially reduce a risk of harm
- The actor's practice must be no broader than necessary
- The actor's practice must satisfy at least one condition from each of the following categories:
  1. Type of risk
  2. Type of harm
  3. Implementation basis
- The practice must satisfy the condition concerning a patient's right to request review of an individualized determination of risk of harm.

# Privacy Exception

- It will not be information blocking if an actor does not fulfill a request to access, exchange, or use EHI in order to protect an individual's privacy, provided certain conditions are met.

## Key Conditions

- To satisfy this exception, an actor's privacy-protected practice must meet at least one of the four sub-exceptions:
  1. Precondition not satisfied
  2. Health IT Developer of certified health IT not covered by HIPAA
  3. Denial of an individual's request for their EHI consistent with 45 CFR 164.524(a) (1) and (2)
  4. Respecting an individual's request not to share information

# Security Exception

- It will not be information blocking for an actor to interfere with the access, exchange, or use of EHI in order to protect the security of EHI, provided certain conditions are met.

## Key Conditions

- 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.
- The practice must either implement a qualifying organizational security policy or implement a qualifying security determination (case by case).

# Infeasibility Exception

- 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.

## Key Conditions

- The practice must meet one of the following conditions:
  1. Uncontrollable events
  2. Segmentation
  3. Infeasibility under the circumstances

## “Under the Circumstances” Deeper Dive

- **(A)** The type of electronic health information and the purposes for which it may be needed;
- **(B)** The cost to the actor of complying with the request in the manner requested;
- **(C)** The financial and technical resources available to the actor;
- **(D)** Whether the actor's practice is non-discriminatory and the actor provides the same access, exchange, or use of electronic health information to its companies or to its customers, suppliers, partners, and other persons with whom it has a business relationship;
- **(E)** Whether the actor owns or has control over a predominant technology, platform, health information exchange, or health information network through which electronic health information is accessed or exchanged; and
- **(F)** Why the actor was unable to provide access, exchange, or use of electronic health information consistent with the exception in § 171.301.

## “Under the Circumstances” Deeper Dive (cont.)

- In determining whether the circumstances were infeasible, it shall not be considered whether the manner requested would have:
  - **(a)** Facilitated competition with the actor
  - **(b)** Prevented the actor from charging a fee or resulted in a reduced fee
- **Responding to requests:** If an actor does not fulfill a request for access, exchange, or use of electronic health information for any of the reasons provided in paragraph (a) of this section, the actor must, within ten business days of receipt of the request, provide to the requestor in writing the reason(s) why the request is infeasible.

# Health IT Performance Exceptions

- It will not be information blocking for an actor to take reasonable and necessary measures to make health IT temporarily unavailable or to degrade the health IT's performance for the benefit of the overall performance of the health IT, provided certain conditions are met.

## Key Conditions

- 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.

# Health IT Performance Exceptions (cont.)

## Key Conditions

- The actor may take action against a third-party app that is negatively impacting the health IT's performance, provided that the practice is:
  1. For a period of time no longer than necessary to resolve any negative impacts;
  2. Implemented in a consistent and non-discriminatory manner; and
  3. Consistent with existing service level agreements, where applicable.
- If the unavailability is in response to a risk of harm or security risk, the actor must only comply with the *Preventing Harm or Security Exception*, as applicable.

## Content and Manner Exception

- It will not be information blocking for an actor to limit the **content** of its response to a request to access, exchange, or use EHI or the **manner** in which it fulfills a request to access, exchange, or use of EHI, provided certain conditions are met.

### Key Conditions

- Content Condition: Establishes the content an actor must provide in response to a request to access, exchange or use EHI in order to satisfy the exception.
- Manner Condition: Establishes the manner in which an actor must fulfill a request to access, exchange, or use EHI in order to satisfy this exception

# Fees Exception

- It will not be information blocking for an actor to charge fees – including fees that result in a reasonable profit margin – for accessing, exchanging, or using EHI, provided certain conditions are met.

## Key Conditions

- The practice must:
  - Meet the basis for the fees condition
  - Not be specifically excluded
  - Comply with Conditions of Certification

# Licensing Exception

- It will not be information blocking for an actor to license interoperability elements for EHI to be accessed, exchanged or used, provided certain conditions are met.



## Key Conditions

- The practice must meet:
  - The negotiating a license conditions
  - The licensing conditions
  - Additional conditions relating to the provision of interoperability elements

# Penalties

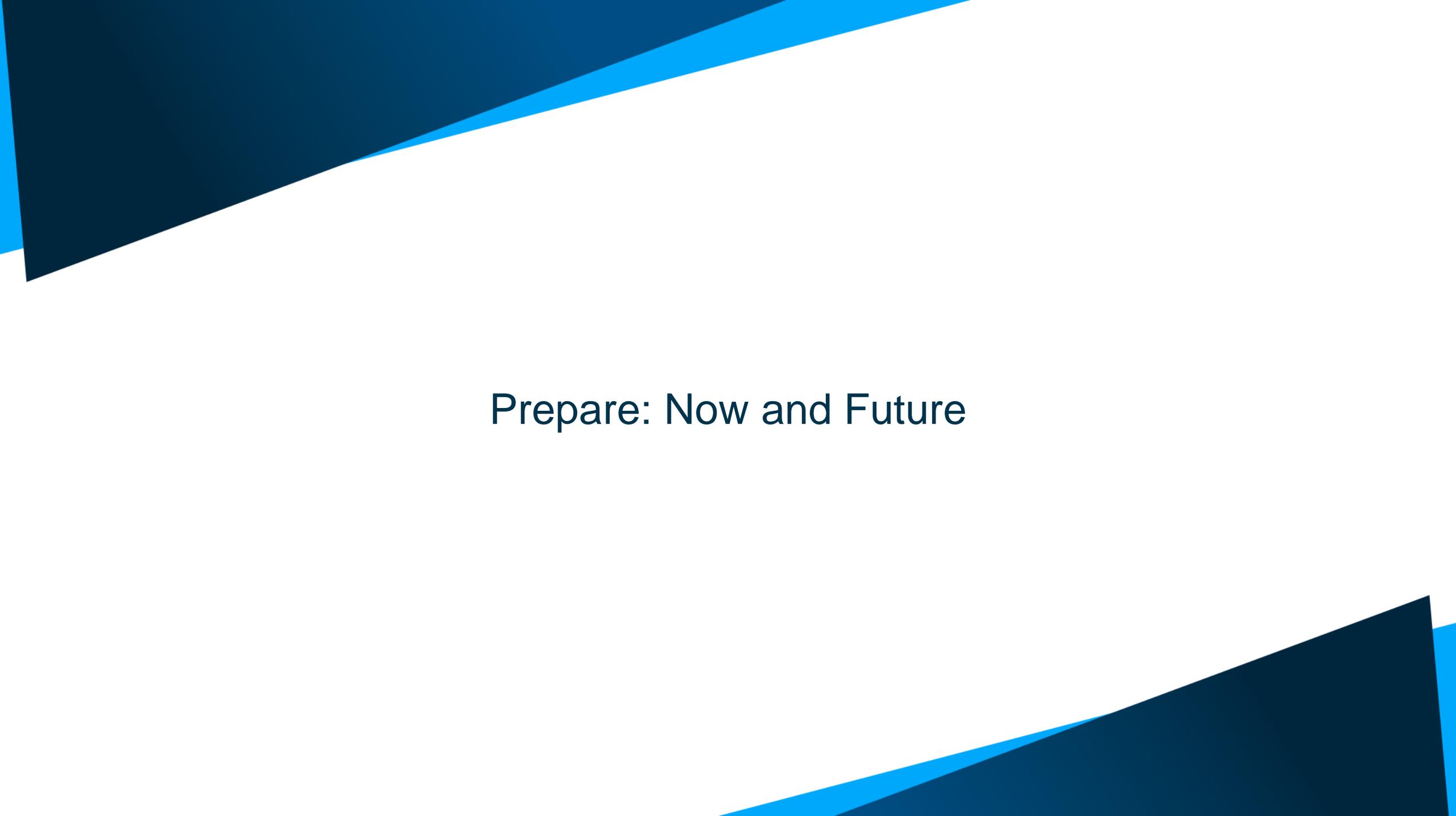
# Non-Compliance Penalties

A semi-transparent white rectangular box containing a login form. The form has an orange 'Login' button at the top, followed by two input fields labeled 'Username :' and 'Password :'. The background of the slide shows a person's hands typing on a laptop keyboard.

Login

Username :

Password :



Prepare: Now and Future

# What Should You Be Doing?

- ✓ Identify whether your organization has a compliance program.
- ✓ Consider defining your organization's reasonableness standard.
- ✓ Developing and documenting scenarios where physicians may take reasonable actions could assist in compliance audits.
- ✓ Develop procedures which provide a detailed workflow for case-by-case findings and documentation of the same.



# What Should You Be Planning?

- ✓ Develop, review, and test.
- ✓ Conduct regular training.
- ✓ Evaluate vendors.



## What Should You Expect from Vendors?

- ✓ Ask for information for complying with the information blocking rules.
- ✓ Consider data segmentation and when Infeasibility and/or Privacy Exceptions should be used.
- ✓ Evaluate your existing policies regarding right to access.
- ✓ Consider adopting a new policy regarding denial of access.
- ✓ Consider the need for additional resources.



# Questions?

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# Thank you!

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