# 5th Annual “Let’s Talk Compliance” Virtual Conference


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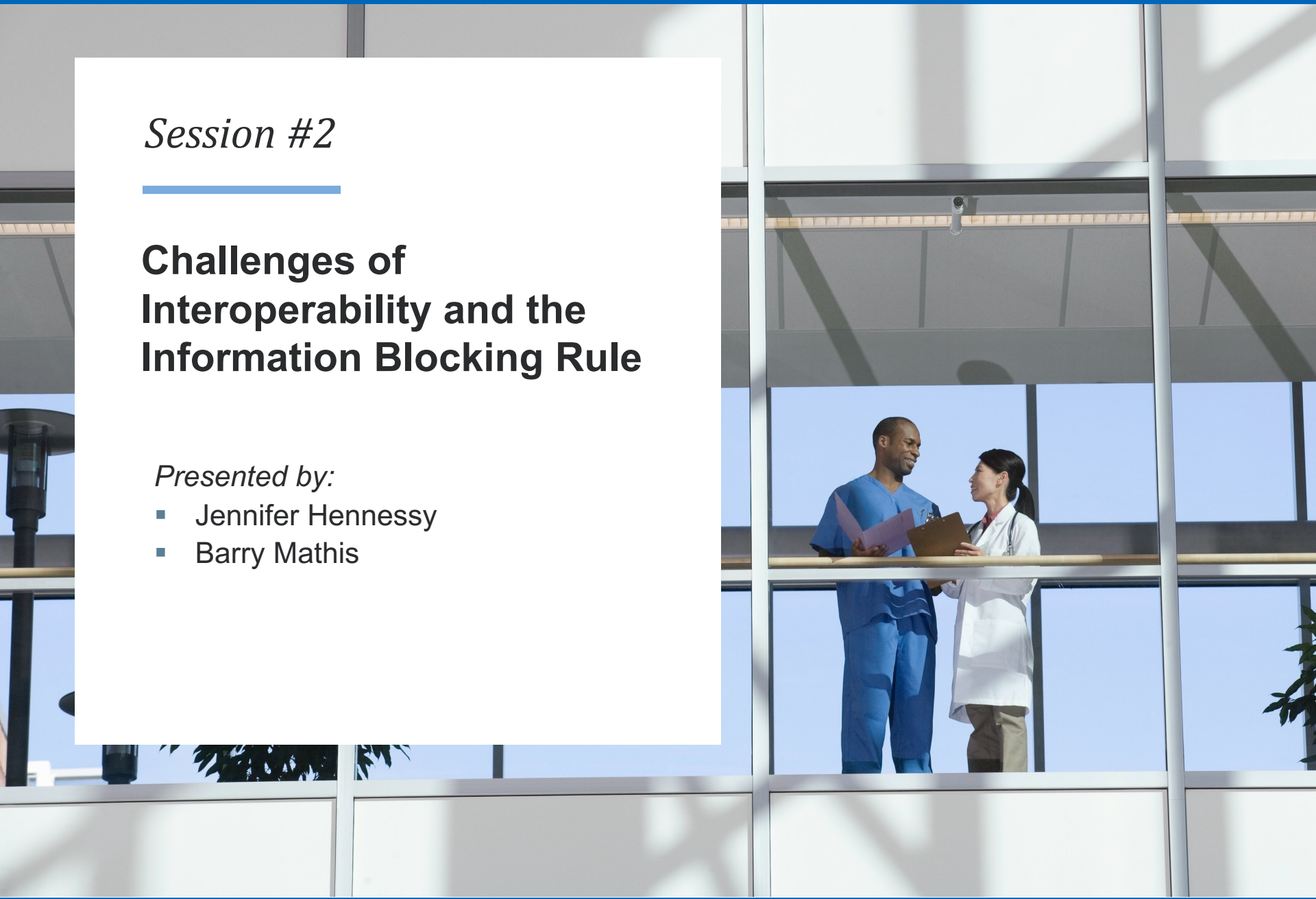

*Session #2*

# Challenges of Interoperability and the Information Blocking Rule

*Presented by:*

- Jennifer Hennessy
- Barry Mathis

# Presentation Overview

**During this session we will provide the following information:**

- Overview of the Information Blocking Rules: who is affected, the type of information affected, requirements, exceptions, and penalties for noncompliance
- Overview of what you should be doing now
- Overview of what you should be planning to do
- Overview of what you should expect from your vendors

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# ONC Information Blocking Rule

# What is Information Blocking?


- Business, technical, and organizational practices that prevent or materially discourage the access, exchange or use of electronic health information (EHI) when an Actor knows, or (for some Actors like EHR vendors) should know, that these practices are likely to interfere with access, exchange, or use of EHI
- If conducted by a health care provider, there must also be knowledge that such practice is unreasonable and likely to interfere with, prevent, or materially discourage access, exchange, or use of EHI

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# Actors: Health Care Providers

- Applies to all providers – not just federal program participants
- A health care provider is a: 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 center; emergency medical services provider; federally qualified health center; group practice; pharmacist; pharmacy; laboratory; physician; practitioner; provider operated by or under contract with the Indian Health Service or by an Indian tribe, tribal organization, or urban Indian organization; rural health clinic; covered entity under 42 U.S.C. 256b; ambulatory surgical center; therapist; and any other category of health care facility, entity, practitioner, or clinician determined appropriate by the HHS Secretary

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# Actors: HINs or HIEs

- An 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 electronic health information:
  - Among more than two unaffiliated individuals or entities (other than the individual or entity to which this definition might apply) that are enabled to exchange with each other; and
  - That is for a treatment, payment, or health care operations purpose, as such terms are defined in 45 CFR 164.501 regardless of whether such individuals or entities are subject to the requirements of 45 CFR parts 160 and 164


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# Actors: Health IT Developers 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 (as that term is defined in 42 U.S.C. 300jj(5)); and
- Which has, at the time it engages in a practice that is the subject of an information blocking claim, one or more Health IT Modules certified under a program for the voluntary certification of health information technology that is kept or recognized by the National Coordinator pursuant to 42 U.S.C. 300jj-11(c)(5) (ONC Health IT Certification Program)

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# What Data? EHI


- EHI = ePHI in a Designated Record Set
- Medical records, billing records, payment and claims records
- Health plan enrollment records
- Case management records
- Other records used, in whole or in part, to make decisions about individuals

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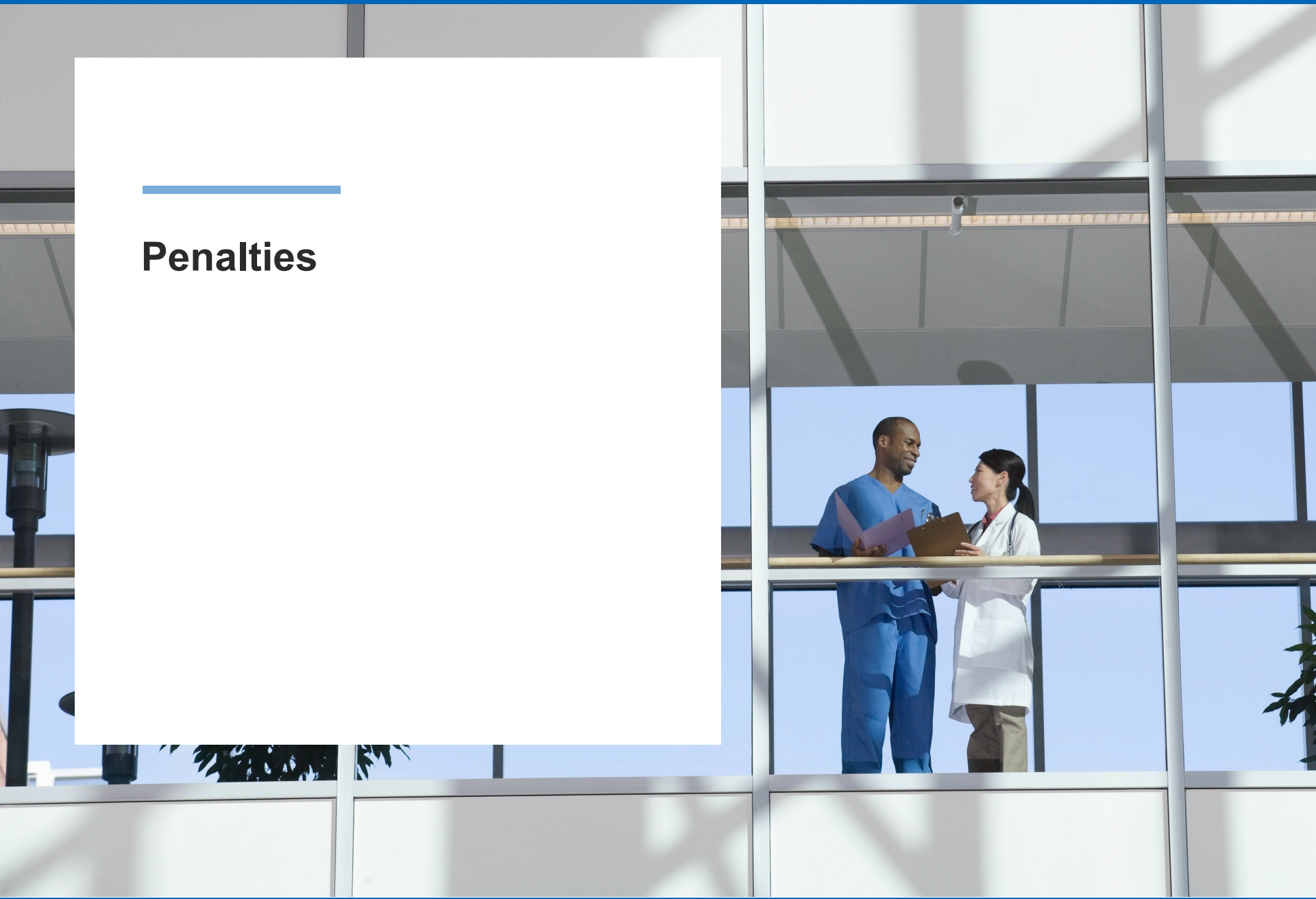
# Penalties



# Non-Compliance Penalties

- Statute establishes a maximum civil monetary penalty of $1,000,000 per violation for non-compliance by health information technology developers, networks and exchanges
- Directs the OIG to refer health care provider non-compliance to the “appropriate agency” for the imposition of “appropriate disincentives”
  - Future rulemaking will define the meaning of “appropriate disincentives”
  - Statute directs HHS to ensure that health care providers are not penalized for the failure of developers of health information technology to meet applicable certification requirements

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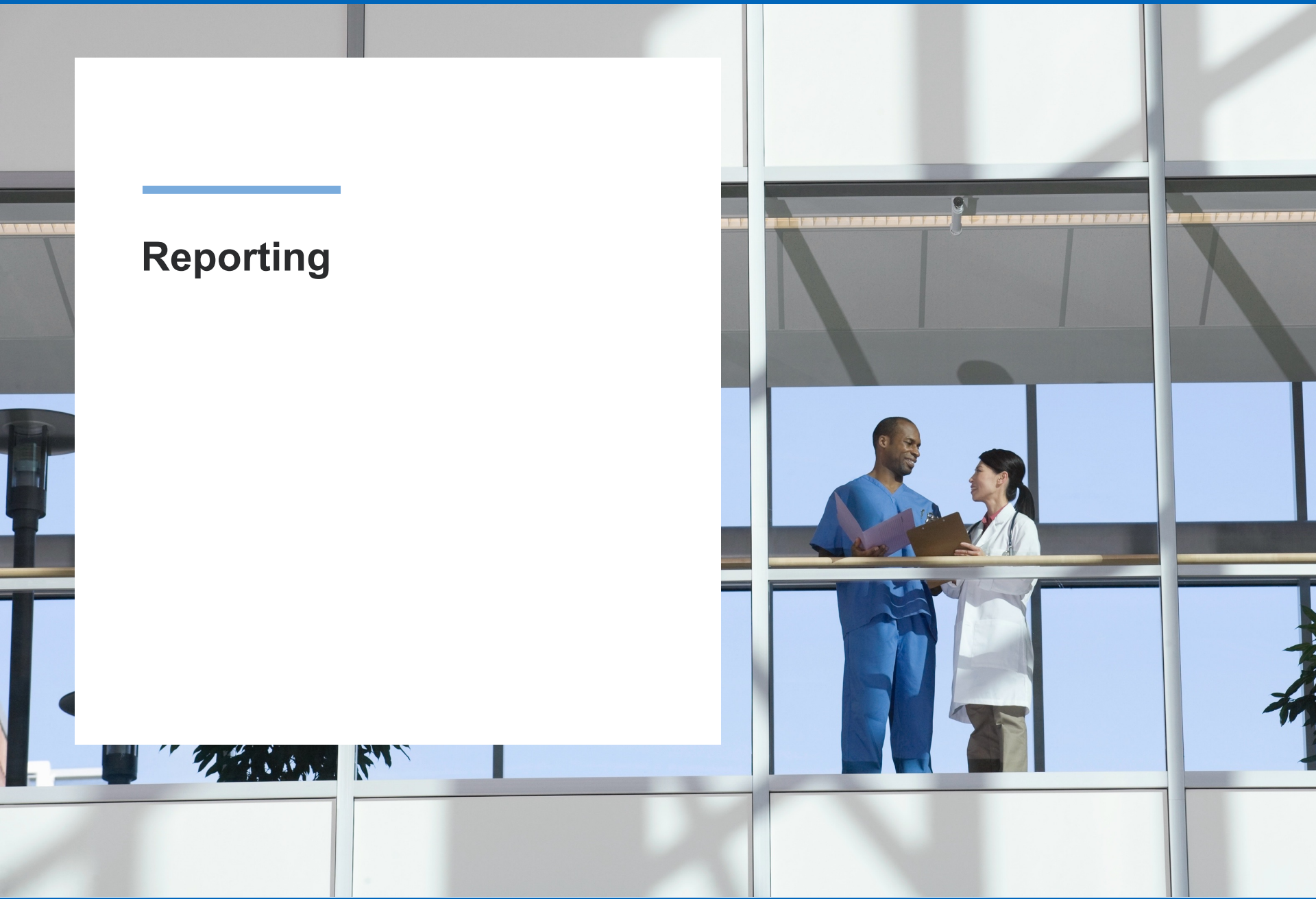
# Reporting



# HHS Soliciting 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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**What is information blocking?** **Information blocking (or data blocking) occurs when individuals or entities — such as healthcare providers or IT vendors — knowingly and unreasonably interfere with the exchange or use of electronic health information.**[1] Information blocking is a serious problem because it can prevent timely access to information needed to manage patients' health conditions and coordinate their care. Further, it can prevent information from being used to improve health, make care more affordable, and research new treatments and cures.

**Identifying information blocking:** Information blocking can happen as a result of overt actions or policies that prevent electronic health information from

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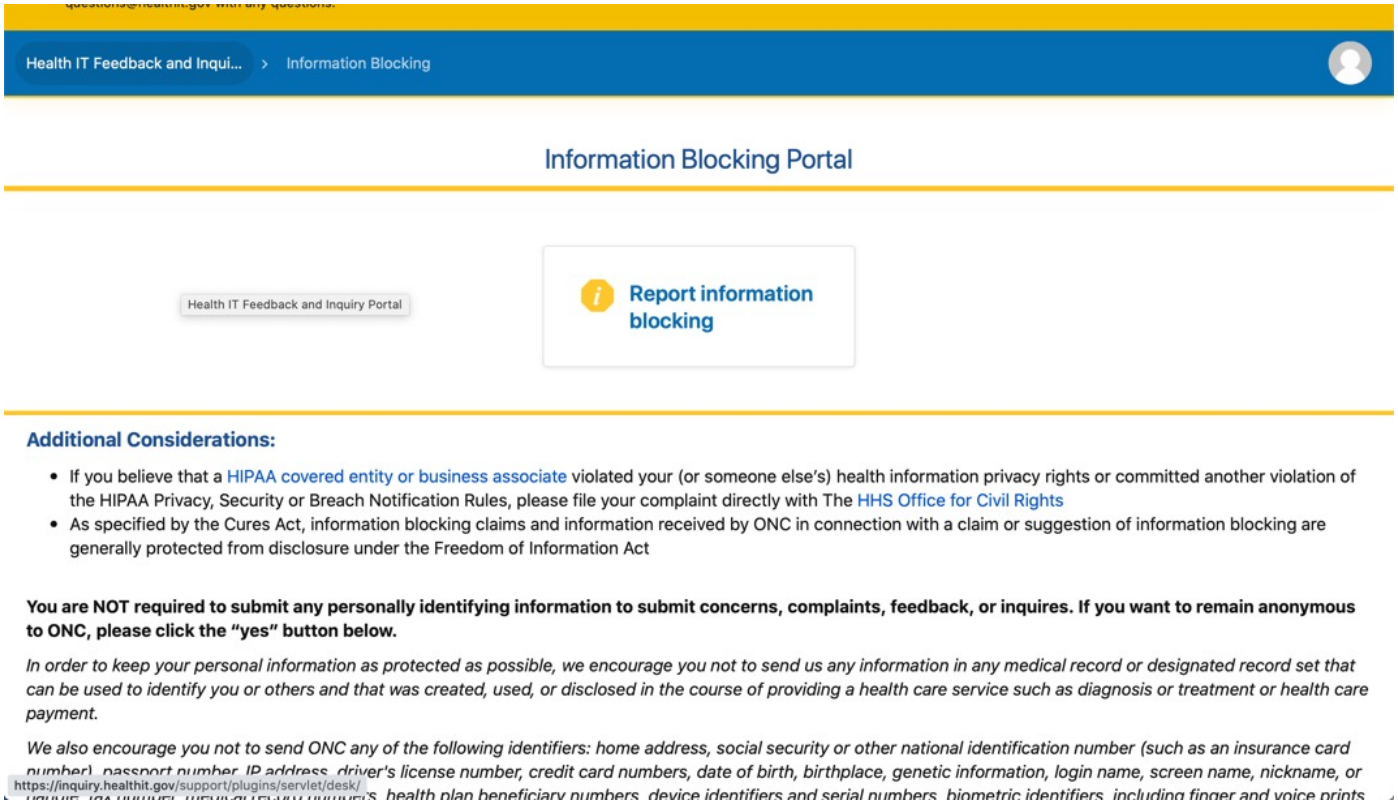
# Info Blocking Portal




[Link to Portal]

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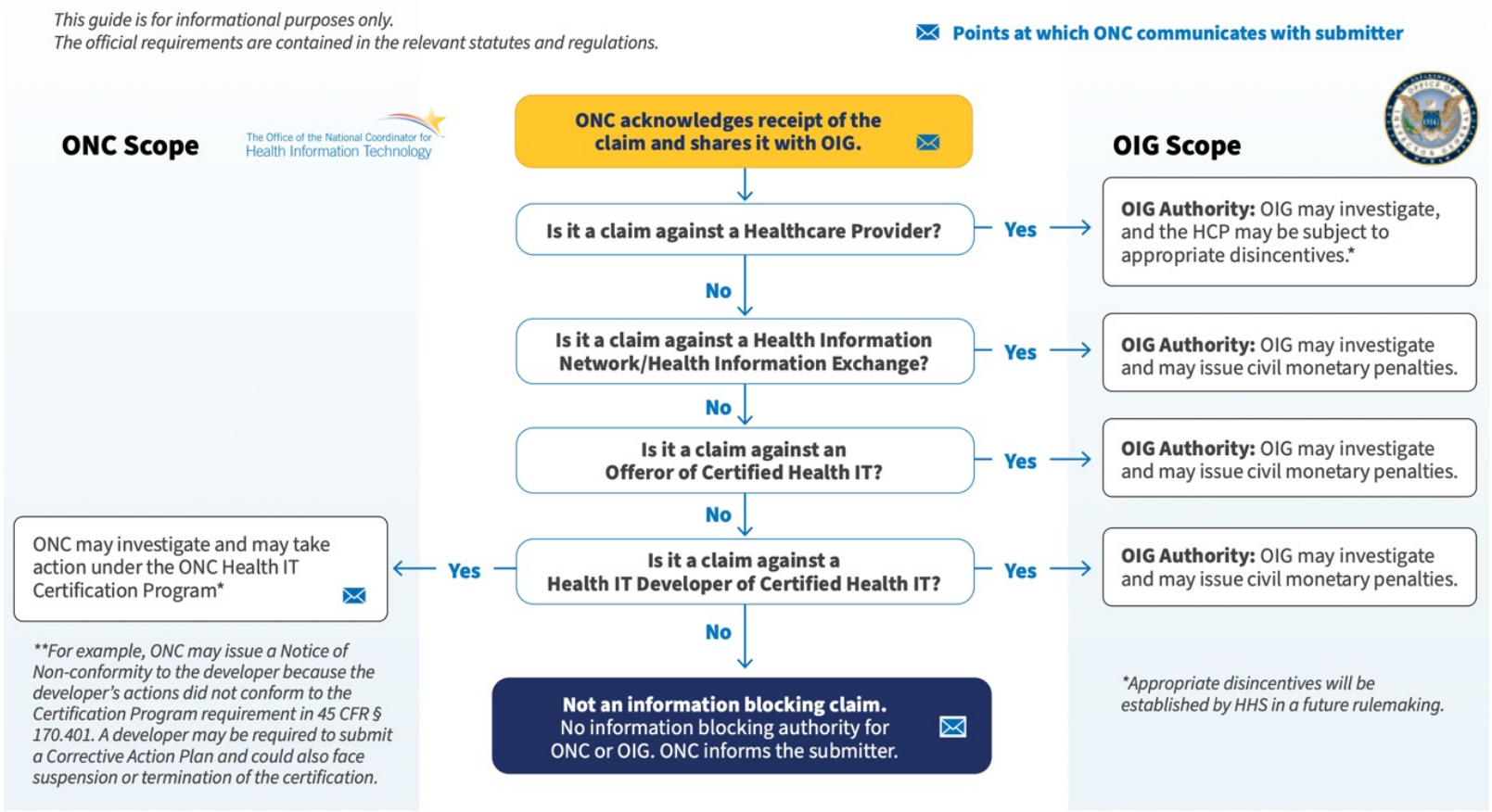
# Reporting and Response

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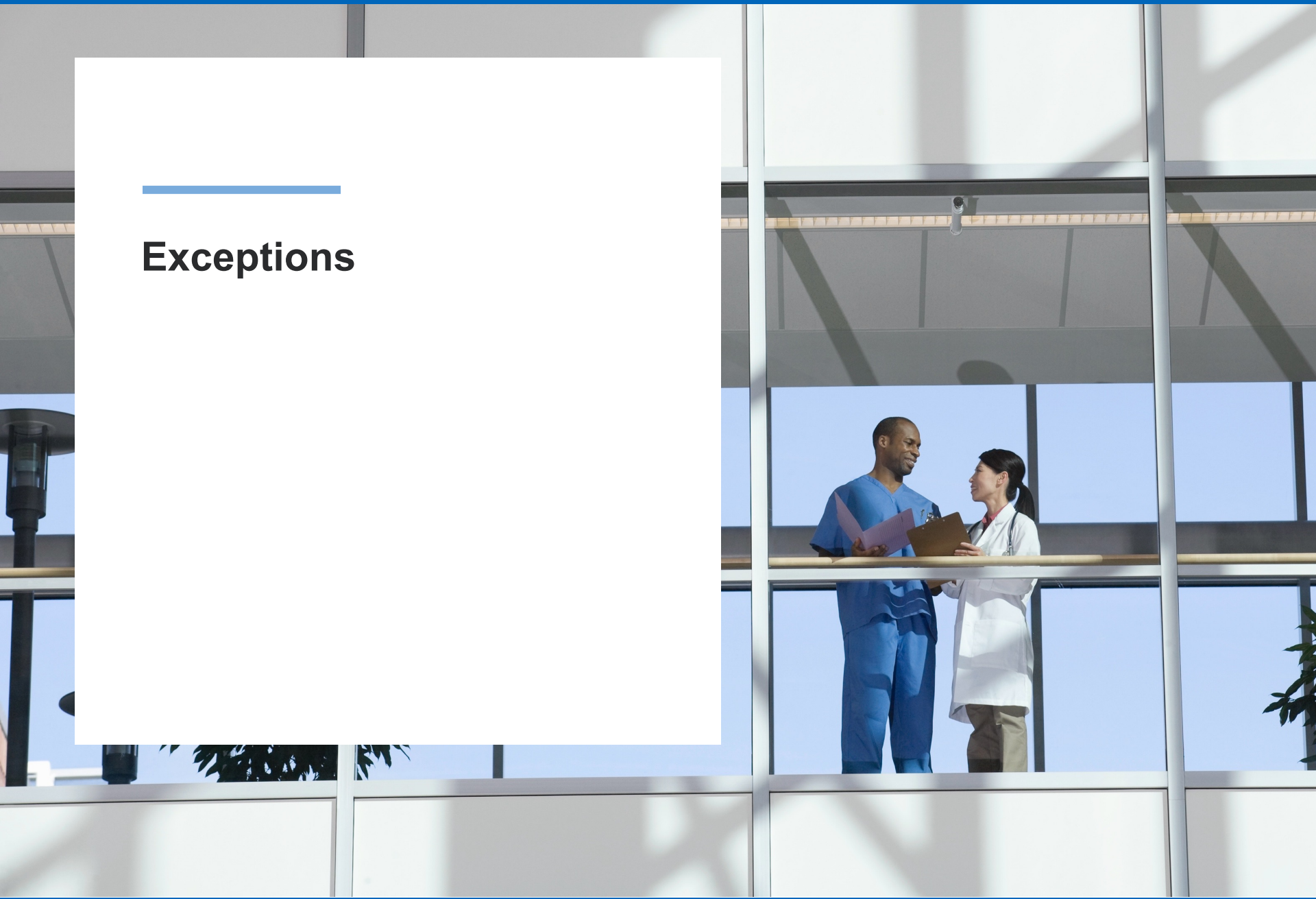
# Exceptions



# Eight Exceptions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# Exceptions

- **The following are not information blocking if certain conditions are met:**

  1. **Content and Manner Exception:** limiting content of response to a request to access, exchange, or use EHI or the manner in which it fulfills a request to access, exchange, or use EHI

     - Must be technically unable to fulfill the request or have failed to reach agreeable terms. Fulfilled via one of three alternative means without unnecessary delay, including a mutually agreed machine-readable format.

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# Exceptions

2. **Fees Exception:** charging fees for access, exchange, or use of EHI, including fees that result in a reasonable profit margin
3. **Licensing Exception:** licensing interoperability elements for EHI to be accessed, exchanged, or used
   - The license must satisfy specified regulatory standards, including, among other things, that the royalty must be reasonable, based solely on the independent value of the technology, and non-discriminatory.

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# Exceptions

4. **Preventing Harm Exception:** engaging in practices that are reasonable and necessary to prevent harm to a patient or another person
5. **Security Exception:** interfering with the access, exchange, or use of EHI in order to protect the security of EHI
6. **Health IT Performance Exception:** taking reasonable and necessary measures to make health IT temporarily unavailable for the benefit of the overall performance of the health IT

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# Exceptions

7. **Privacy Exception:** not fulfilling a request to access, exchange, or use EHI in order to protect an individual's privacy
   - If permitted under privacy laws to provide access, exchange, or use of EHI, then the Information Blocking Rules state the provider should do so. However, not required to use or disclose EHI if prohibited under federal or state privacy laws.
8. **Infeasibility Exception:** not fulfilling a request to access, exchange, or use EHI due to the infeasibility of the request
   - Not required to fulfill request for access, exchange, or use of EHI if requested EHI cannot be unambiguously segmented from EHI that cannot be shared.

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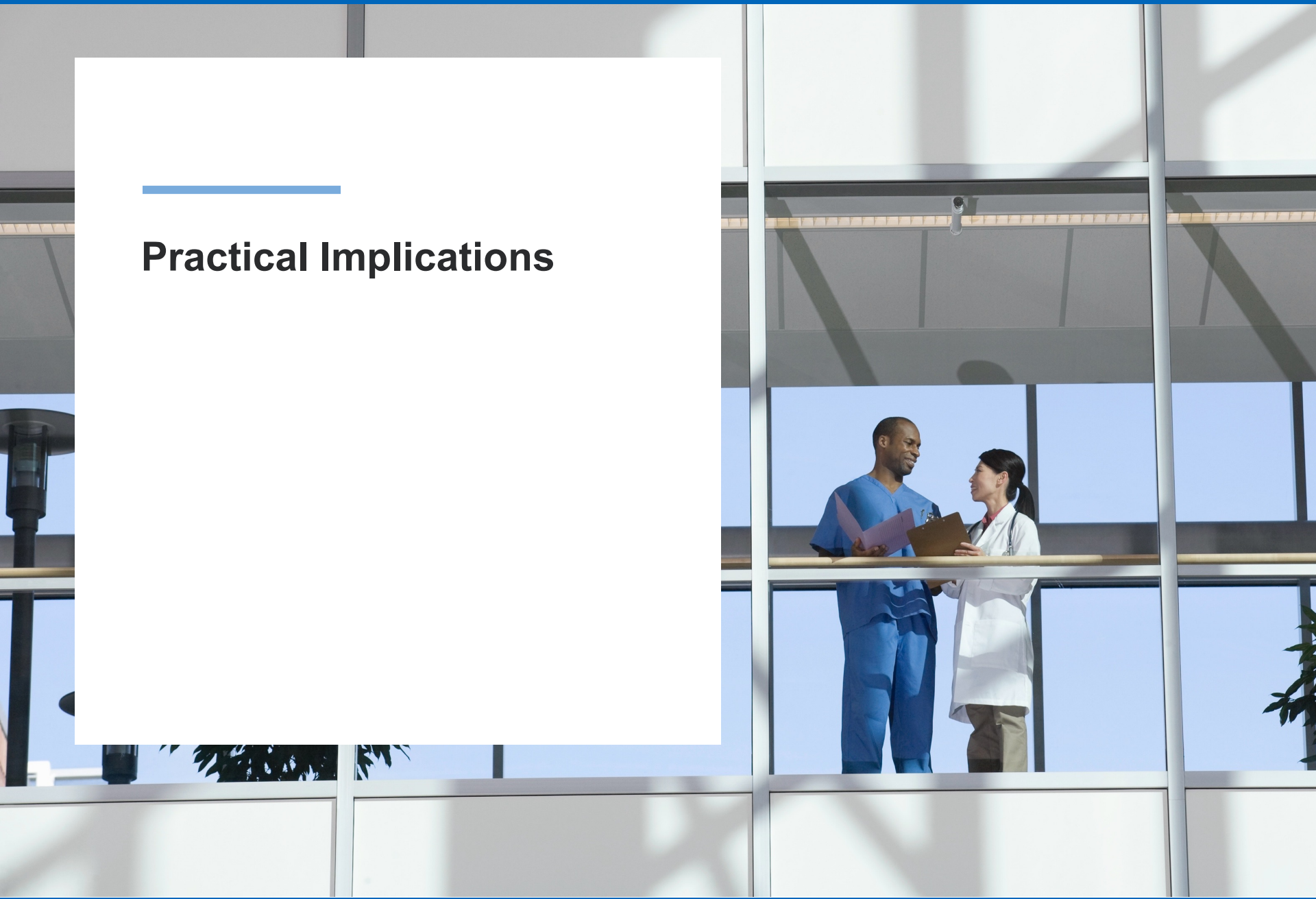
# Practical Implications



# Practical and Implementation Considerations

- **Turns HIPAA on its head** by requiring health care providers and their business associates to share data in most instances where HIPAA permits, but does not require, the disclosure
- HIPAA **historically** required business associate agreements to establish permissible uses and disclosures of PHI and to prohibit uses and disclosures not permitted or required by law
- **Now,** when the law **permits** the access to or exchange of EHI, disclosure often will be **required**

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# Practical and Implementation Considerations

- Covered entities and their business associates should **update their privacy and security policies** and modify their release of information and data-sharing practices that prohibit or delay that data sharing
- In several places, the rule requires that organizational **policies be in writing (for example, in the Preventing Harm, Privacy and Security Exceptions**)

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# Practical and Implementation Considerations

- Although the ONC notes that the Information Blocking Rule does not itself require actors to violate their BAAs and associated service level agreements, Actors **cannot use these agreements to limit EHI disclosures in an arbitrary manner**
- Will take time for changes to **work their way through BAAs**
- Consider applicability of BAA language regarding **modifications to laws**

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# Practical and Implementation Considerations

- Rule requires in several places that the policies be implemented in a **consistent and non-discriminatory manner**
- If delay or denial of information may be considered interference, **compliance with an exception** may be necessary to avoid information blocking claims
- The Information Blocking Rule will place **pressure on all Actors to streamline their technology and data contracting protocols** for technology tools and data sharing projects involving EHI

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# Practical and Implementation Considerations: Expectations for EHR Vendors

- Ask for information from your EHR vendor on their **compliance** with the information blocking rules
- Consider whether and how your EHR will support **data segmentation** (e.g., based on a patient's preference or because protected EHI cannot be separated from the office note to comply with state or federal law) and when the Infeasibility and/or Privacy Exceptions should be used

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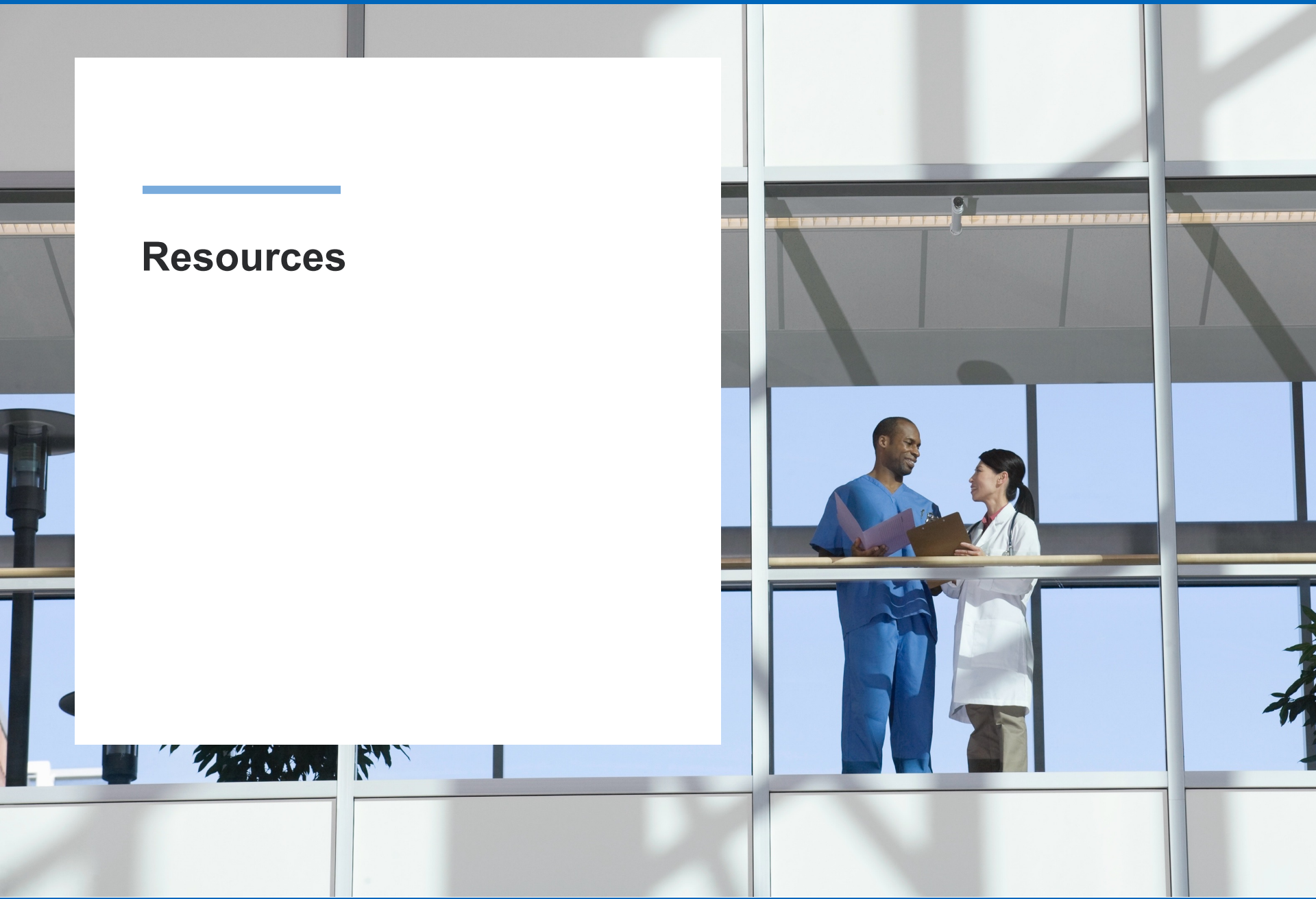
# Resources



# Fact Sheets, FAQs, Webinars, etc.

- https://www.healthit.gov/topic/information-blocking

## Information Blocking Resources

ONC publishes blogs, journal articles, and data briefs on a regular basis to ensure everyone can easily stay current with the latest findings and learnings from our work across the health IT ecosystem.

Fact Sheets | FAQs | Blogs | Webinars & Presentations | Press/Media

- **Information Blocking Definition**
- **Information Blocking Terms Defined**
- **Information Blocking Actors** [PDF - 244KB]
- **Health Care Provider Definition** [PDF - 446KB]
- **Information Blocking Exceptions** [PDF - 567KB]
- **Highlighted Regulatory Dates – Information Blocking Provisions** [PDF - 330KB]
- **United States Core Data for Interoperability v1** [PDF - 934KB]
- **Understanding Electronic Health Information (EHI)** [PDF - 344KB]
- **Understanding the Scope of Electronic Health Information (EHI) for the Purposes of the Information Blocking Definition** [PDF - 344KB]
- **Information Blocking Portal Process** [PDF - 233KB]

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Jennifer Hennessy is a data privacy and cybersecurity attorney. She advises clients, ranging from multinational corporations to startups, on all aspects of compliance with international, federal and state data privacy and security laws. This includes assisting covered entities and business associates in complying with Health Insurance Portability and Accountability Act (HIPAA) and advising organizations on compliance with federal law 42 C.F.R. Part 2 (Confidentiality of Alcohol and Drug Abuse Treatment Records), the California Consumer Privacy Act (CCPA), the EU's General Data Protection Regulation (GDPR), the Family Educational Rights and Privacy Act (FERPA) and the Gramm–Leach–Bliley Act (GLBA).

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Leading the Information Technology Advisory Services at PYA, Barry has three decades of experience in IT and the healthcare industry as a Chief Information Officer, Chief Technology Officer, senior IT audit manager, and IT risk management consultant. He has performed and managed complicated technology assessments, EMR implementations, security audits, and hundreds of contract negotiations for some of the most sophisticated hospital systems in the country. Barry is a member of the United States Marine Corps, the Health Care Compliance Association, the Association of Healthcare Internal Auditors, the Healthcare Information Management Systems Society, and the Audit and Control Association.

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# Thank you



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