

# INFORMATION BLOCKING RULE



Kim Stanger

(6/23)

# DISCLAIMER

This presentation is designed to provide general information on pertinent legal topics. The information is provided for educational purposes only. Statements made or information included do not constitute legal or financial advice, nor do they necessarily reflect the views of Holland & Hart LLP or any of its attorneys other than the author.

This information contained in this presentation is not intended to create an attorney-client relationship between you and Holland & Hart LLP. Substantive changes in the law subsequent to the date of this presentation might affect the analysis or commentary. Similarly, the analysis may differ depending on the jurisdiction or circumstances. If you have specific questions as to the application of the law to your activities, you should seek the advice of your legal counsel.

# TODAY'S PRESENTER



**Kim C. Stanger**

Partner, Holland & Hart LLP

(208) 383-3913

[kcstanger@hollandhart.com](mailto:kcstanger@hollandhart.com)

Kim Stanger is a partner in the Boise office of Holland & Hart LLP and the chair of the firm's Health Law Group. Mr. Stanger helps clients navigate complex state and federal regulations and practical uses facing the healthcare industry, including transactional, compliance, and administrative matters.

He is consistently named as one of the Best Lawyers in America® for Health Care Law by U.S. News and a Mountain States Super Lawyer. He has been repeatedly awarded the Best Lawyers® Health Care Law "Lawyer of the Year" for Boise. This year, the Idaho Business Review listed him as one of the Leaders in the Law. He is a member of the American Health Law, Past President of the Idaho Bar Association Health Law Section, and a frequent author and speaker on health law-related issues.

# OVERVIEW

- Info Blocking Rule
- Penalties
- Covered entities
- Prohibited activities
- Exceptions
- Proposed Rule
- Interaction with HIPAA
- Program will be recorded.
- If you have questions:
  - Submit them using chat feature, or
  - E-mail me at [kcstanger@hollandhart.com](mailto:kcstanger@hollandhart.com).

# WRITTEN MATERIALS

- Stanger, *Healthcare Providers: Beware New Information Blocking Rule*, <https://www.hollandhart.com/health-care-providers-beware-new-information-blocking-rule>.
- Information Blocking Final Rule, 85 FR 25790 (5/1/20), <https://www.govinfo.gov/content/pkg/FR-2020-05-01/pdf/2020-07419.pdf>
- ONC Fact Sheet, *Information Blocking Actors*, <https://www.healthit.gov/cures/sites/default/files/cures/2020-03/InformationBlockingActors.pdf>
- ONC Fact Sheet, *Information Blocking Exceptions*, <https://www.healthit.gov/cures/sites/default/files/cures/2020-03/InformationBlockingExceptions.pdf>

# 21<sup>ST</sup> CENTURY CURES ACT (2016)

- Designed to enable the exchange of electronic health info (“EHI”) to facilitate better outcomes, lower costs, and greater patient access to health info.
  - Promotes interoperability of health info technology (“IT”).
  - **Prohibits information blocking.**

# 21<sup>ST</sup> CENTURY CURES ACT (42 USC 300JJ-52(B)(2))

## **Developers, networks, and exchanges**

“Any [health IT developer, network, or exchange] that the Inspector General ... determines to have committed information blocking shall be subject to a civil monetary penalty determined by the Secretary for all such violations identified through such investigation, which may not exceed \$1,000,000 per violation.”

## **Providers**

“Any [healthcare provider] determined by the Inspector General to have committed information blocking shall be referred to the appropriate agency to be subject to appropriate disincentives using authorities under applicable Federal law, as the Secretary sets forth through notice and comment rulemaking.”

# INFO BLOCKING RULE ("IBR")

- Prohibits “actors” from engaging in any practice that is likely to interfere with, prevent, or materially discourage access, or otherwise inhibit the access, exchange, or use of electronic health information unless—
  - Action is required by applicable law, or
  - Fit within regulatory exception

(45 CFR part 171; *see also* 42 USC 300jj-52(a))



# ACTORS

- Healthcare providers
  - Physician, practitioner or therapist; hospital; nursing facility; group practice; clinic, ASC, FQHC, RHC, laboratory, others?
- Developers of certified health IT
  - Individual or actor that develops or offers certified health IT, other than a health care provider that self-develops health IT for its own use.
- Health info networks or exchanges (“HIN/HIE”)

(42 U.S.C. 300jj; 45 CFR 171.102)

# ELECTRONIC HEALTH INFO ("EHI")

Electronic health info =

- ePHI under HIPAA that would be included in a designated record set regardless of whether EHI are used or maintained by or for a covered entity as defined in 45 CFR 160.103.
- Does not include:
  - Psychotherapy notes as defined in 45 CFR 164.501.
    - Psych notes = personal notes prepared by therapist or practitioner separate from healthcare record.
  - Info compiled in reasonable anticipation of, or for use in, a civil, criminal, or administrative action or proceeding.

(45 CFR 171.102)

# PENALTIES

## HEALTH IT DEVELOPERS, HIN, HIE

- Complaints to ONC
  - <https://www.healthit.gov/topic/information-blocking>.
- ONC investigations
- Proposed rule:
  - Civil monetary penalties of up to \$1,000,000 per violation(85 FR 22979, proposed 42 CFR 1003.1420)
- Others?

## HEALTHCARE PROVIDERS

- “Appropriate disincentives to be established by HHS.”
- No proposed rule yet.



# 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.

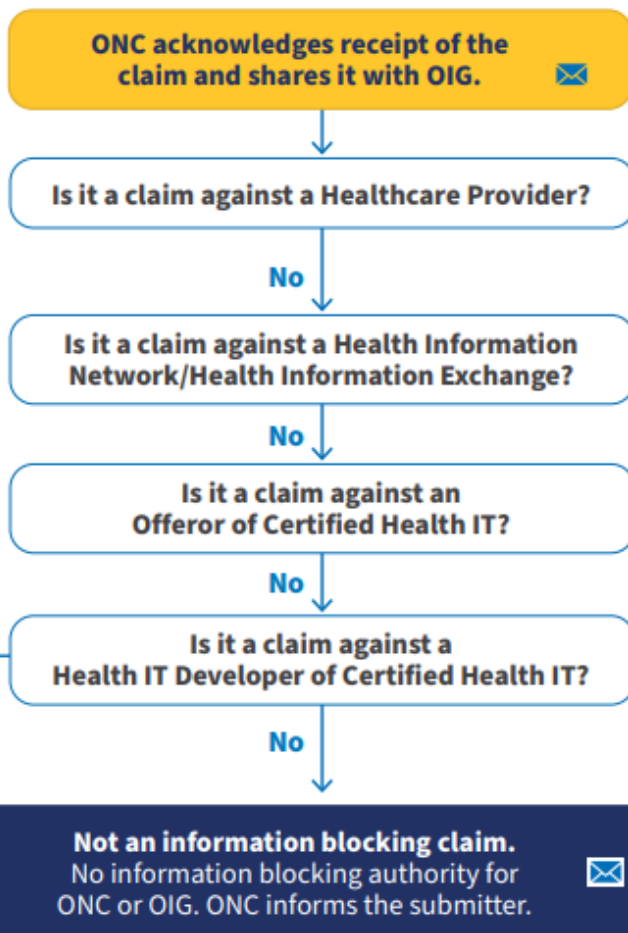
✉ Points at which ONC communicates with submitter

## ONC Scope



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.

**OIG Authority:** OIG may investigate and may issue civil monetary penalties.

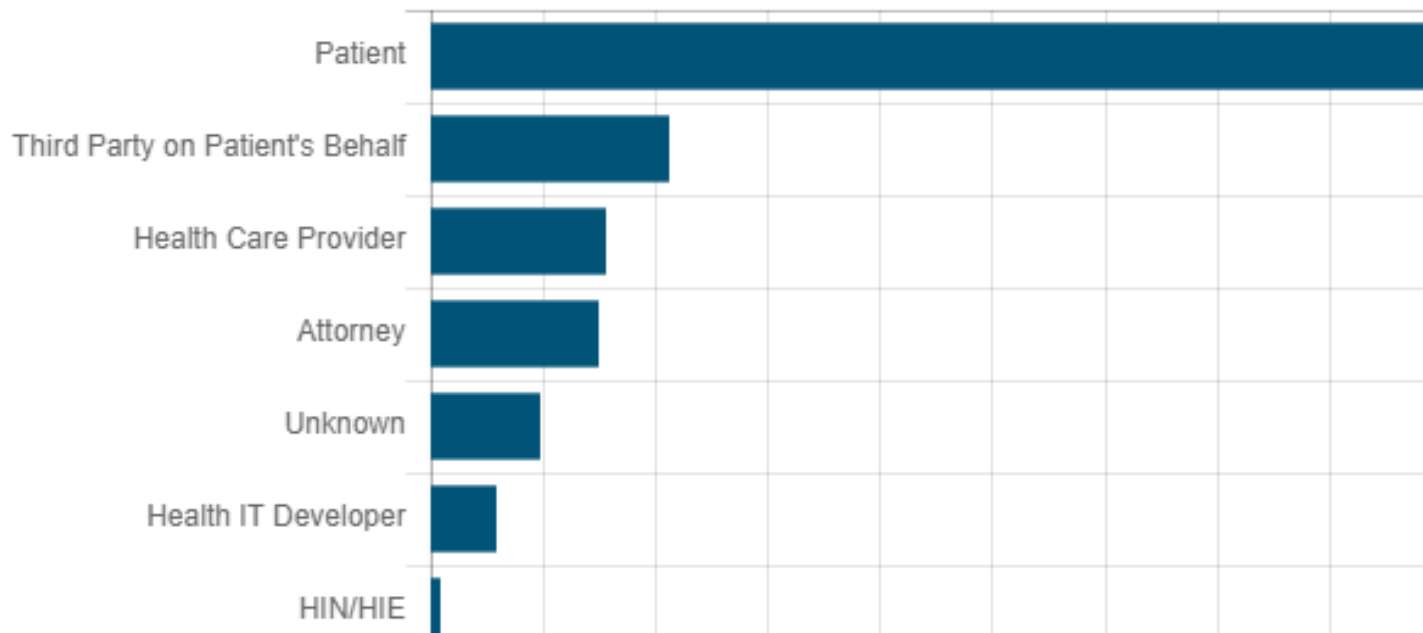
**OIG Authority:** OIG may investigate and may issue civil monetary penalties.

\*Appropriate disincentives will be established by HHS in a future rulemaking.

## Information on submissions received through the Report Information Blocking Portal<sup>2</sup>

|  |     |
|--|-----|
| Total number of information blocking portal submissions received   | 764 |
| Total number of possible claims of information blocking  | 708 |
| Total number of submissions received that did not appear to be claims of potential information blocking <sup>3</sup> | 56  |

## Claims Counts by Types of Claimant



# KNOWLEDGE STANDARD

## Health IT developer, HIE, HIN

- Developer knows or should know that such practice is likely to interfere with, prevent, or materially discourage access, exchange, or use of EHI.

(45 CFR 171.103(a)(2))

## Health care provider:

- Provider knows that such practice is unreasonable and is likely to interfere with, prevent, or materially discourage access, exchange, or use of EHI.

(45 CFR 171.103(a)(3))

# INFO BLOCKING EXAMPLES

- Refusing to timely respond to requests for EHI from patients or others.
- Requiring patient's written consent for EHI when not required by HIPAA.
- Charging excessive fees to obtain EHI.
- Imposing unreasonable administrative hurdles before sharing EHI.
- Imposing unreasonable contract terms that prohibit sharing EHI, e.g., EHR agreements, BAAs, etc.
- Implementing health IT in nonstandard ways that increase the burden.
- Others?

# NOT INFO BLOCKING

- Action does not interfere with access.
- Action required by law.
  - HIPAA, 42 CFR part 2, state privacy laws, etc.
  - Laws require conditions before disclosure and conditions are not satisfied, e.g., patient authorization.
- Action is reasonable under the circumstances.
- Action fits within regulatory exception.



# INFO BLOCKING EXCEPTIONS



# INFO BLOCKING EXCEPTIONS

Exceptions that involve fulfilling requests to access, exchange, or use EHI.

1. Content and manner exception
2. Fees
3. Licensing

Exceptions that involve NOT fulfilling requests to access, exchange, or use EHI.

1. Preventing harm
2. Privacy
3. Security
4. Infeasibility
5. Health IT performance

# EXCEPTIONS: PREVENTING HARM

- Actor may block EHI if it has a reasonable belief that the practice will substantially reduce a risk of harm to a patient or other person, *e.g.*, to avoid the risk that corrupt or inaccurate data will be incorporated in the patient's electronic health record, or upon a determination by a licensed healthcare professional that disclosure is likely to endanger life or physical safety of the patient or others.
- Specific criteria that must be satisfied when evaluating the reasonableness of the practice and the risk of harm.

(45 CFR 171.201; see 85 FR 25821-44)

# EXCEPTIONS: PROTECTING PRIVACY

- Actor may block EHI if:
  - state or federal privacy laws impose preconditions to access that have not been satisfied;
  - HIPAA allows the actor to deny access to the individual; or
  - the patient has requested that her/his info not be shared.
- In each of these situations, the actor must satisfy additional regulatory conditions.

(45 CFR 171.202; see 85 FR 25844-25859)

# EXCEPTIONS: PROTECTING SECURITY

- Actor may block EHI if necessary to safeguard the confidentiality, integrity and availability of the EHI consistent with
  - its organizational security policies, or
  - a specific determination that there are no reasonable, less obstructive alternatives to secure the EHI.

(45 CFR 171.203; see 85 FR 25859-65)

# EXCEPTIONS: ACCESS INFEASIBLE

- Actor may block access to EHI if:
  - extraordinary circumstances beyond control prevent actor from fulfilling the request;
  - the actor cannot segregate the requested EHI from other info that is not subject to access; or
  - the actor demonstrates that responding to the request is not feasible due to, *e.g.*, the type of information, cost, available resources, control of the relevant platform, *etc.*
- Within ten (10) days of the request, the actor must notify the requestor in writing of the reason for failing to provide the access requested.

(45 CFR 171.204; see 85 FR 25865-70)

# EXCEPTIONS: HEALTH IT PERFORMANCE

- Actor may temporarily block access to EHI if necessary for maintenance and improvement of the health IT.

(45 CFR 171.205; see 85 FR 25870-75)

# EXCEPTIONS: CONTENT AND MANNER

- Actor must generally provide access to the EHI content in the manner requested unless the actor is technically unable to fulfill the request or cannot reach agreeable terms with the requestor to fulfill the terms; however, the limits on fees or licenses described below do not apply.
- If the actor cannot grant access as requested or agreed, the actor must take reasonable steps to fulfill the request in an alternative manner consistent with specified technical standards.

(45 CFR 171.301; see 85 FR 25875-79)



# EXCEPTIONS: FEES

- An actor may charge reasonable fees for accessing, exchanging or using EHI so long as they are based on the provider's costs and applied in a non-discriminatory manner as more fully described in the regulations.

(45 CFR 171.302; see 85 FR 25879-88).

# EXCEPTIONS: LICENSING

- Actor may license interoperability elements so long as the actor begins licensing negotiations within ten days from the request and the license satisfies specified regulatory standards.
- Among other things, any royalty must be reasonable, and the license terms must be non-discriminatory.

(45 CFR 171.303; *see* 85 FR 25888-97)



**CURES ACT FINAL RULE**

## Information Blocking Exceptions

**Section 4004 of the 21<sup>st</sup> Century Cures Act (Cures Act) defines practices that constitute information blocking *and* authorizes the Secretary of Health and Human Services (HHS) to identify reasonable and necessary activities that do not constitute information blocking (referred to as “exceptions”).**

On behalf of HHS, ONC has defined **eight** exceptions that offer actors (i.e., health care providers, health IT developers, health information networks (HINs) and health information exchanges (HIEs)) *certainty* that, when their practices with respect to accessing, exchanging, or using electronic health information (EHI) meet the conditions of one or more exceptions, such practices will not be considered information blocking.

An actor’s practice that does not meet the conditions of an exception will not automatically constitute information blocking. Instead such practices will be evaluated on a case-by-case basis to determine whether information blocking has occurred.

We have finalized **eight** exceptions that are divided into two categories:

- Exceptions that involve not fulfilling requests to access, exchange, or use EHI; and
- Exceptions that involve procedures for fulfilling requests to access, exchange, or use EHI.

**Exceptions that involve not fulfilling requests to access, exchange, or use EHI**

Preventing Harm Exception

Privacy Exception

Security Exception

Infeasibility Exception

Health IT Performance Exception

**Exceptions that involve procedures for fulfilling requests to access, exchange, or use EHI**

Content and Manner Exception

Fees Exception

Licensing Exception

# SUMMARY:

## “IS IT INFORMATION BLOCKING?”

Whether info blocking occurred in a particular case depends on whether:

- the individual or entity engaging in the practice is an "actor" as defined in 45 CFR 171.102;
- the claim involves "EHI" as defined in 45 CFR 171.102;
- the practice was required by law;
- the actor's practice met the conditions of an exception under 45 CFR 171;
- the practice rose to the level of an interference under 45 CFR 171; and,
- the actor met the requisite knowledge standard.
  - **Providers:** “knows that such practice is unreasonable and is likely to interfere with access, exchange, or use of electronic health information.”
  - **Health IT developers, HINs, and HIEs:** “knows, or should know, that such practice is likely to interfere with access, exchange, or use of electronic health information.”

(ONC FAQ, available at <https://www.healthit.gov/curesrule/resources/information-blocking-faqs>).



## Frequently Asked Questions

### Filter By

#### Topic

- Information Blocking (51)

#### Categories

- Information Blocking – General (7)
- Actors (7)
- Electronic Health Information (9)
- Interference (12)
- Exceptions – General (2)
- Content And Manner Exception (1)
- Privacy Exception (3)
- Preventing Harm Exception (6)
- Enforcement (2)
- Reporting Claims Of Information

## Frequently Asked Questions

Filter

Recently added/changed

- Any - ▾

Apply

Select to Print All Information Blocking FAQs

### Information Blocking

#### Information Blocking – General

How would any claim or report of information blocking be evaluated? +

Are contractual fees for the export of electronic health information (EHI) using technology that is not certified to 45 CFR 170.315(b)(10) enforceable if the fees were agreed to prior to the applicability date of the information blocking provision? +

On April 5, 2021, can prior agreements, arrangements, or contracts still in effect implicate the information blocking definition in 45 CFR 171? +

# IBR PREEMPTS CONTRACT TERMS

- **On April 5, 2021, can prior agreements, arrangements, or contracts still in effect implicate the information blocking definition in 45 CFR 171?**
- Yes. On and after April 5, 2021, any actor's agreements, arrangements, or contracts are subject to and may implicate the information blocking regulations in 45 CFR part 171.

<https://www.healthit.gov/faqs?f%5B0%5D=subtopic%3A7016>)

# EHI AND PAPER RECORDS

- **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...?**
- Yes, an individual's request for a copy of their 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 implicate the information blocking regulations.  
(<https://www.healthit.gov/faqs?f%5B0%5D=subtopic%3A7016>)
- But would not apply to purely paper records.

# DRAFT NOTES

- **Is non-final clinical information, such as draft clinical notes or incomplete test results that are pending confirmation, included in the definition of electronic health information (EHI) for purposes of the information blocking regulations?**
- It depends.... [I]f such data are used to make health care decisions about an individual then that data would fall within the definition of “designated record set” (see 45 CFR § 164.501), and therefore within the definition of EHI. To the extent a data point falls within the definition of EHI, practices likely to interfere with legally permissible access, exchange or use of that EHI could implicate the information blocking definition.

([https://www.healthit.gov/faqs?facets\\_query=](https://www.healthit.gov/faqs?facets_query=))



# REQUIRING IT UPGRADE?

- **Do the information blocking regulations require actors to have or use certified health IT, or upgrade the certified health IT they already have, in order to fulfill a request to access, exchange, or use electronic health information?**
- No. The information blocking regulations do not require actors to have or use health IT certified under the ONC Health IT Certification Program....  
(<https://www.healthit.gov/faqs?f%5B0%5D=subtopic%3A7016>)
- But participation in other programs might.

# REQUIRING PROACTIVE PROVISION OF EHI

- **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?**
- “Proactively” or “proactive” is not a regulatory concept included within the information blocking regulations.
- While the information blocking regulations do not require actors to proactively make electronic health information (EHI) available, once a request to access, exchange or use EHI is made actors must timely respond to the request....

([https://www.healthit.gov/faqs?facets\\_query=](https://www.healthit.gov/faqs?facets_query=))

# REQUEST FOR ACCESS?

- **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?**
- No. Facts and circumstances will determine whether the information blocking regulations are implicated....
- [A]ny act or omission, whether or not in response to a request for access, exchange, or use of EHI, could implicate the information blocking regulation if the act or omission interferes with, prevents, or materially discourages the access, exchange, or use of EHI. For example, ... the practice of implementing health information technology in ways that are likely to restrict access, exchange, or use of EHI with respect to exporting complete information sets or transitioning between health IT systems could be considered information blocking.
- [T]he practice of including a contract provision that restricts access, exchange, or use of EHI could, under certain circumstances, implicate the information blocking regulations...
- [O]missions ... could similarly implicate the information blocking regulations under certain circumstances [e.g.,] failure to exchange EHI; failure to make EHI available for use; and not complying with another law that requires access, exchange, or use of EHI.

([https://www.healthit.gov/faqs?facets\\_query=](https://www.healthit.gov/faqs?facets_query=))

# FULFILLING REQUESTS

- **Is an actor required to fulfill a request for access ... with all the EHI they have for a patient or should the amount of EHI be based on the details of the request?**
- The fulfillment of a request for access, exchange or use of EHI, including what EHI is shared, should be based on the request. However, any activity by the actor that seeks to artificially restrict or otherwise influence the scope of EHI that may be requested may constitute interference and could be subject to the information blocking regulation in 45 CFR part 171.

([https://www.healthit.gov/faqs?facets\\_query=](https://www.healthit.gov/faqs?facets_query=))

# FULFILLING REQUESTS

- **[W]hat if an actor only maintains some of the requested information electronically?**
- In terms of fulfilling requests for EHI, it is important to remember that the requirement to fulfill requests for access, exchange, and use of EHI is in any case limited to what the actor may, under applicable law, permissibly disclose in response to a particular request. Under the information blocking regulations ..., the actor is only required to fulfill a request with the requested EHI that they have and that can be permissibly disclosed to the requestor under applicable law. However, for protected health information they have, but do not maintain electronically, all HIPAA requirements would still be applicable, including the right of access.

([https://www.healthit.gov/faqs?facets\\_query=](https://www.healthit.gov/faqs?facets_query=))

# DELAYS

- **Are actors (for example, health care providers) expected to release test results to patients through a patient portal or application programming interface (API) as soon as the results are available to the ordering clinician?**
- [O]nce a request to access, exchange or use EHI is made actors must timely respond to the request (for example, from a patient for their test results). Delays or other unnecessary impediments could implicate the information blocking provisions.
- In practice, this could mean a patient would be able to access EHI such as test results in parallel to the availability of the test results to the ordering clinician.

([https://www.healthit.gov/faqs?facets\\_query=](https://www.healthit.gov/faqs?facets_query=))

# DELAYS

- **Likely** to be an Interference
  - It would likely be ... an interference ... if a health care provider established an organizational policy that, for example, imposed delays on the release of lab results for any period of time 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....
  - [W]here 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.
  - [W]here a delay occurs in providing a patient's EHI via an API to an app that the patient has authorized to receive their EHI.

([https://www.healthit.gov/faqs?facets\\_query=](https://www.healthit.gov/faqs?facets_query=))

# DELAYS

- **Unlikely** to be an Interference
  - If the delay is necessary to enable the access, exchange, or use of EHI, it is unlikely to be considered an interference under the definition of information blocking...
  - [I]f the release of EHI is delayed in order to ensure that the release complies with state law, it is unlikely to be considered an interference so long as the delay is no longer than necessary ....
  - [I]n scenarios where EHI must be manually retrieved and moved from one system to another system...

([https://www.healthit.gov/faqs?facets\\_query=](https://www.healthit.gov/faqs?facets_query=))



# DELAY REQUIRED BY OTHER LAWS

- **Is it information blocking when state law requires a specific delay in communication of EHI, or that certain information be communicated to the patient in a particular way, before the information is made available to the patient electronically?**
- No. The definition of information blocking ... does not include practices that interfere with access, exchange or use of EHI when they are specifically required by applicable law.... To the extent the actor's practice is likely to interfere with access, exchange, or use of EHI beyond what would be specifically necessary to comply with applicable law, the practice could implicate the information blocking definition.

([https://www.healthit.gov/faqs?facets\\_query=](https://www.healthit.gov/faqs?facets_query=))

# DELAY PERMITTED BY OTHER LAWS

- **When a state or federal law or regulation, such as the HIPAA Privacy Rule, requires EHI be released by no later than a certain date after a request is made, is it safe to assume that any practices that result in the requested EHI's release within that other required timeframe will never be considered information blocking?**
- No. The information blocking regulations have their own standalone provisions. The fact that an actor ... meets its obligations under another law applicable to them or its circumstances (such as the maximum allowed time an actor has under that law to respond to a patient's request) will not automatically demonstrate that the actor's practice does not implicate the information blocking definition.
- If an actor who could more promptly fulfill requests for legally permissible access, exchange, or use of EHI chooses instead to engage in a practice that delays fulfilling those requests, that practice could constitute an interference under the information blocking regulation, even if requests affected by the practice are fulfilled within a time period specified by a different applicable law.

[https://www.healthit.gov/faqs?facets\\_query=](https://www.healthit.gov/faqs?facets_query=)

# CHARGING FEES

- **If an individual asks an actor to provide a copy of the individual's electronic health information (EHI) ... may any fees be charged?**
- Yes.... [A]ny fee charged for providing ... access to EHI that does not meet the Fees Exception (45 CFR 171.302) potentially could be considered information blocking. We have consistently interpreted the broad definition of information blocking ... to encompass potentially any fee that is likely to interfere with, prevent, or materially discourage the access, exchange, or use of EHI (84 FR 7521, 85 FR 25880). This would include any fees charged to individuals for copies of their EHI furnished on paper or on electronic media (such as CDs or USB drives)....

<https://www.healthit.gov/faqs?f%5B0%5D=subtopic%3A7016>

# PATIENT REQUESTS NO DISCLOSURE

- **If an individual requests that their EHI not be disclosed, is it information blocking if an actor does not disclose the EHI based on the individual's request?**
- No, if the actor's conduct satisfies the requirements of the information blocking regulations, such as the Privacy Exception.... For example, the sub-exception Respecting an Individual's Request Not to Share Information permits an actor, unless the disclosure is required by law, to honor an individual's request not to provide access, exchange, or use of the individual's EHI, which aligns with the individual's right to request a restriction on disclosures of their protected health information under the HIPAA Privacy Rule (45 CFR 164.522(a)(1)).

([https://www.healthit.gov/faqs?facets\\_query=](https://www.healthit.gov/faqs?facets_query=))

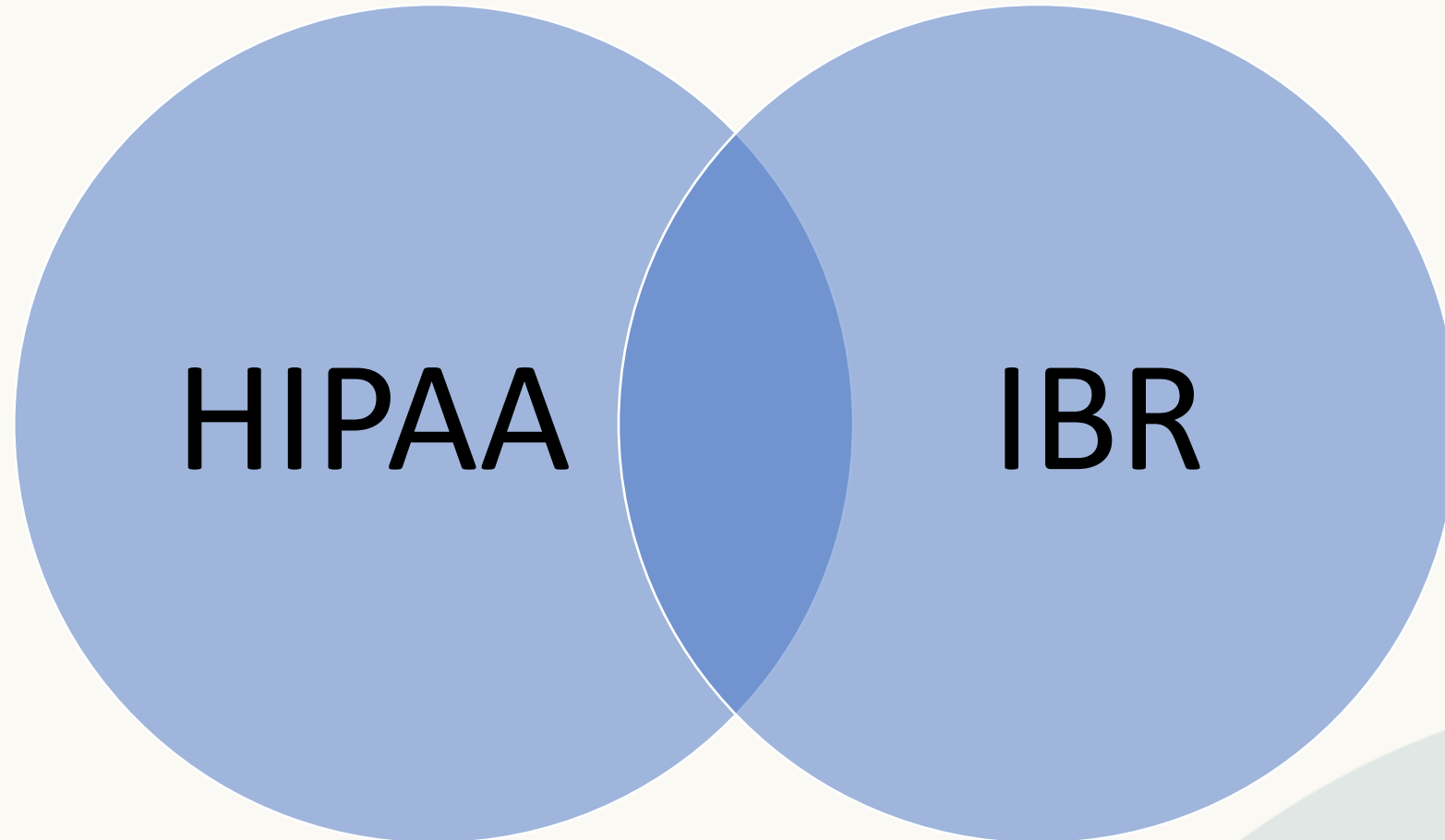
# LAW PROHIBITS ACCESS OR DISCLOSURE

- **Would it be information blocking if an actor does not fulfill a request to access, exchange, or use EHI in order to comply with federal privacy laws that require certain conditions to have been met prior to disclosure?**
- No, it would not be information blocking if the actor's practice of not fulfilling a request in such circumstances meets the Privacy Exception (45 CFR 171.202). All actors remain responsible for disclosing EHI only when the disclosure is allowed under all applicable federal laws. For example, actors who are HIPAA covered entities or business associates must comply with the HIPAA Privacy Rule and any other applicable federal laws that limit access, exchange, or use of EHI in particular circumstances. Adherence to such federal laws is not information blocking, if the other conditions of the Privacy Exception are also met.

(<https://www.healthit.gov/faqs?f%5B0%5D=subtopic%3A7016>)

- But may be info blocking if federal law permits access or disclosure.

# INFO BLOCKING AND HIPAA



# INFO BLOCKING AND HIPAA

## If HIPAA allows access or disclosure:

- IBR prohibits info blocking.
- IBR may require provider to allow access or disclosure even if HIPAA does not require it, e.g.,
  - Treatment, payment, operations.
  - Authorization.
- IBR may require quicker response than HIPAA.
  - > 30 days.

## If HIPAA or other law prohibits disclosure:

- Not info blocking if conditions for access or disclosure are not satisfied, e.g.,
  - Patient consent.
  - Patient authorization.
  - Confirmation that HIPAA exception allows disclosure.

# PROPOSED CHANGES TO IBR

- Proposed rule would:
  - Narrow what it means to “offer” health IT for developers.
  - Confirm that healthcare providers who self-develop certified health IT are not “developers” if outside definition of “offering” health IT.
  - Confirms IBR applies to all EHI, not just USCDI data elements.
  - Modify certain exceptions, e.g.,
    - Infeasibility exception
    - Manner exception

(88 FR 23857-23875)



# PROPOSED CHANGES TO HIPAA

- Strengthened individual’s right of access.
  - Allows individuals to take notes or use other personal devices to view and capture images of PHI.
  - Must respond within 15 days.
  - Requires providers to share info when directed by patient.
  - Further limits charges for producing PHI.
- Facilitates individualized care coordination.
- Clarifies the ability to disclose to avert threat of harm.
- Not required to obtain acknowledgment of Notice of Privacy Practices (“NPP”).
- Modifies content of NPP.

(86 FR 6446)

# NEXT STEPS



# NEXT STEPS

- Take advantage of new rule.
  - Look for opportunities to improve through greater access to info, including care coordination, data, etc.
  - Request data you may need/want.
  - Market to patients or others?
- Confirm your status as an “actor”
  - Healthcare provider
  - Health IT developer, HIN, HIE
    - Beware internally developed health IT that you make available to others.
- Identify and educate stakeholders.
  - Administration, technology, information systems, medical records, compliance, contracting, marketing, etc.

# NEXT STEPS

- Review EHR functionality
  - Enable data sharing functionality that may have been deactivated.
  - Evaluate scope of ability to respond to requests.
  - Identify situations that may justify denials.
- Review relevant contracts
  - Ensure they do not contain improper limitations.
  - Vendor contracts, e.g., licensing agreements, IT services, data storage or processing, software development, etc.
  - Contracts you send out, e.g., business associate agreements, etc.
  - *May need to educate contractors and/or push back against terms that constitute information blocking.*

# NEXT STEPS

- Review and modify electronic health info practices
  - Requests for access or sharing by patients.
  - Requests for access or sharing by other healthcare providers.
  - Requests for access or sharing by other third parties, e.g., payees, competitors, etc.
  - Establish process for routing and reviewing requests by qualified person(s).
  - *Remember: HIPAA still applies, but the Info Blocking Rule limits your ability to deny otherwise permissible disclosures under HIPAA.*
  - *Beware: automatic delays to access (e.g., labs), automatic denials, unwarranted delays, etc.*
- Respond appropriately to requests for access or sharing.
  - Time, content, denials, conditions, etc.

# NEXT STEPS

- Watch for further developments and guidance
  - Enforcement rules
    - Health IT developers, HIN, HIE
    - Healthcare providers
  - ONC direction
  - Proposed HIPAA modifications, e.g.,
    - Reduced time for responding to requests
    - Sharing e-PHI
    - Others?
  - Others?

# ADDITIONAL RESOURCES





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

Official Website of The Office of the National Coordinator for Health Information Technology (ONC)

HealthIT.gov

TOPICS ▾ BLOG NEWS ▾ DATA ABOUT ONC ▾ 🔍

HealthIT.gov > Topics > Information Blocking

## Information Blocking

Most clinical information is digitized, accessible, and shareable thanks to several technology and policy advances making interoperable, electronic health record systems widely available. In 2016, the 21st Century Cures Act (Cures Act) made sharing electronic health information the expected norm in health care by authorizing the Secretary of Health and Human Services (HHS) to identify "reasonable and necessary activities that do not constitute information blocking." ONC's 2020 Cures Act Final Rule established information blocking exceptions to implement the law.



### What Is Information Blocking and to Whom Does It Apply?

Information blocking is a practice by an "actor" that is likely to interfere with the access, exchange, or use of electronic health information (EHI), except as required by law or specified in an information blocking exception. The Cures Act applied the law to healthcare providers, health IT developers of certified health IT, and health

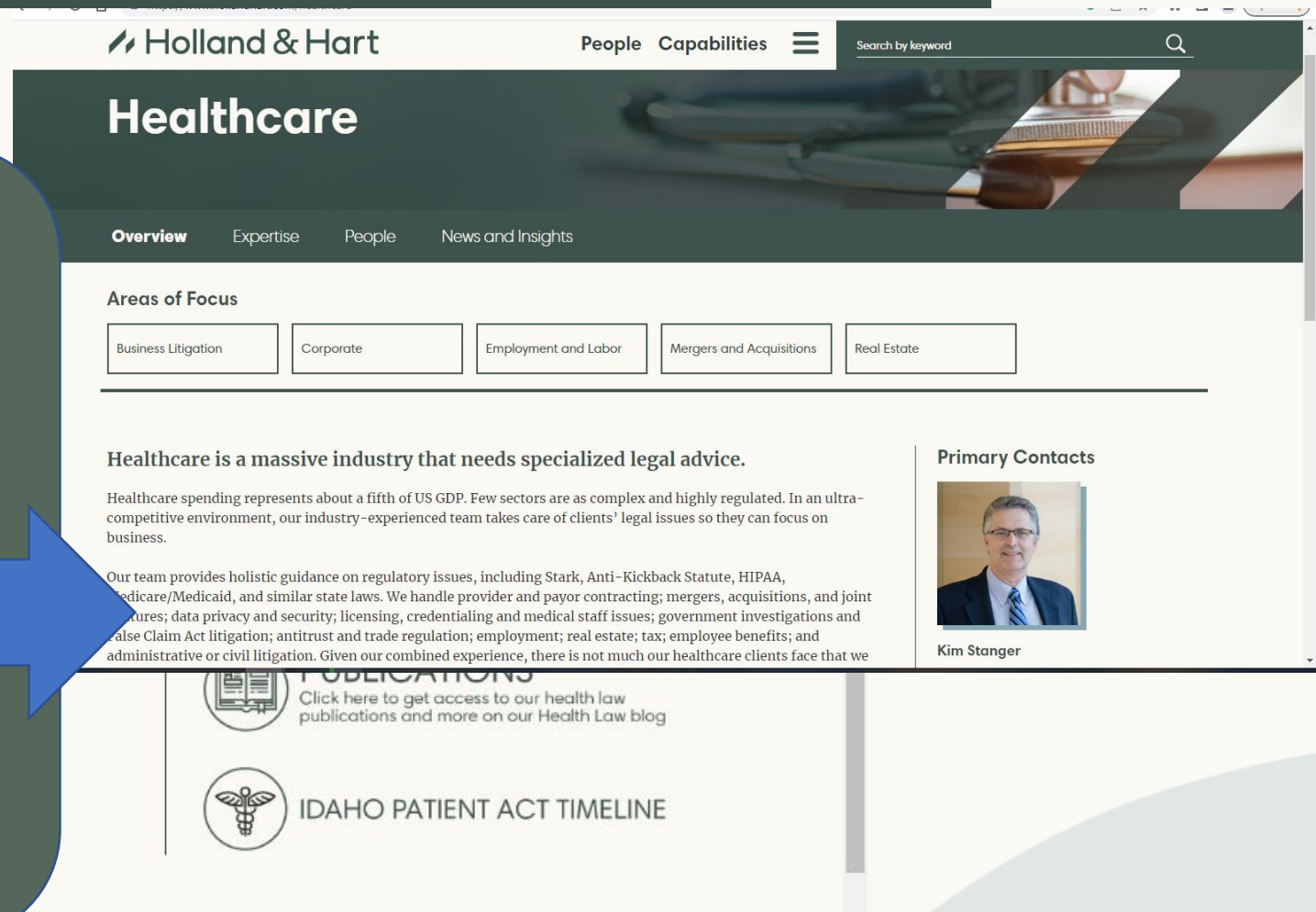
- IBR requirements
- Fact Sheets
  - Actors
  - EHI
  - Exceptions
- FAQs
- Blogs
- Webinars



# [HTTPS://WWW.HOLLANDHART.COM/HEALTHCARE](https://www.hollandhart.com/healthcare)

Free content:

- Recorded webinars
- Client alerts
- White papers
- Other



# QUESTIONS?



Kim C. Stanger  
Office: (208) 383-3913  
Cell: (208) 409-7907  
[kcstanger@hollandhart.com](mailto:kcstanger@hollandhart.com)