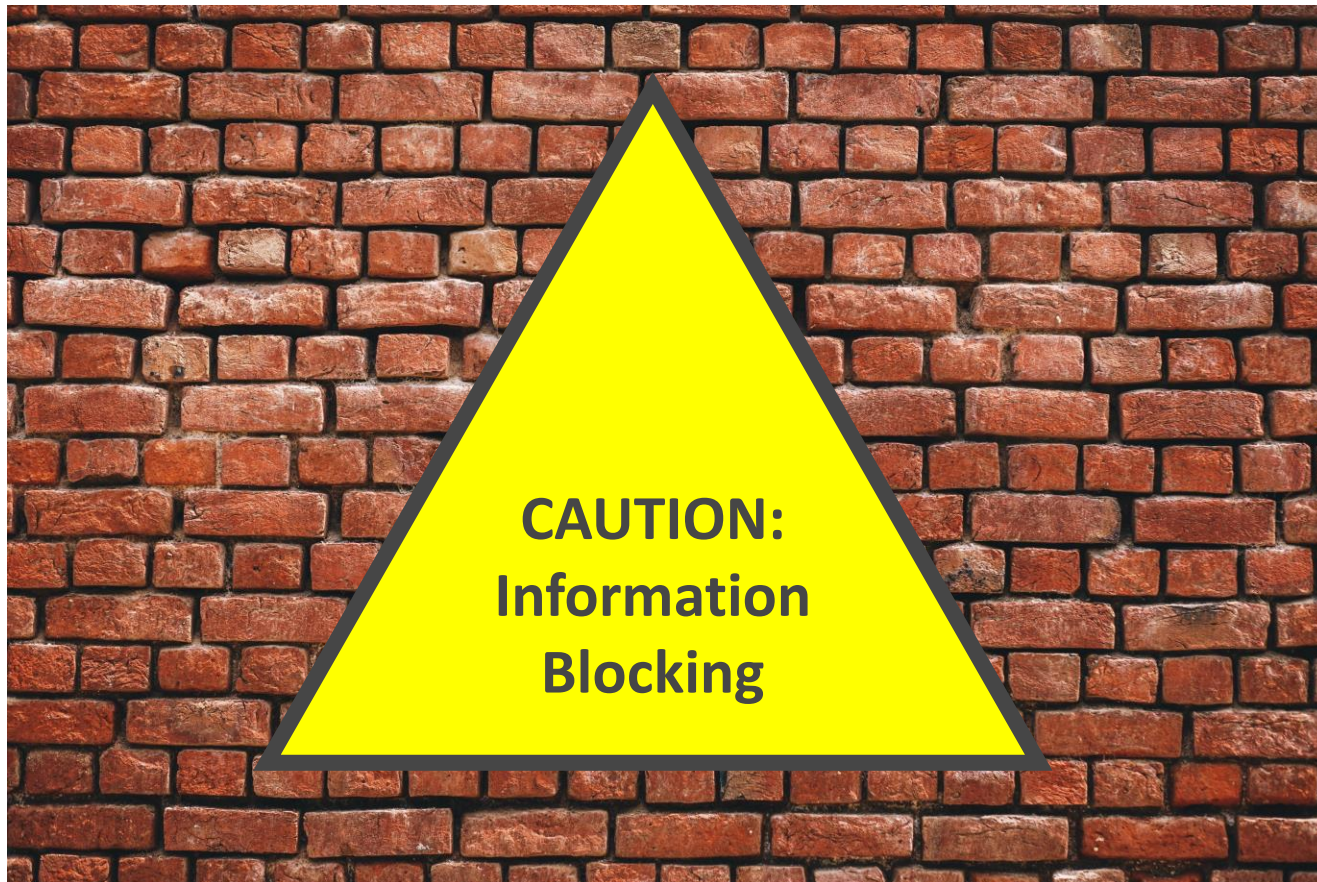


21ST CENTURY CURES ACT: ONC'S INFORMATION BLOCKING RULE



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WHY YOU SHOULD PAY ATTENTION: PENALTIES

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 (4/24/2020); proposed 42 CFR § 1003.1420)
- Others?

Healthcare Providers

- “Appropriate disincentives to be established by HHS.”



ONC INFO BLOCKING RULE

- 21st Century CURES Act (December 13, 2016)
- Title IV directed Office of the National Coordinator for Health Information Technology (ONC) to promulgate rules prohibiting information blocking.
- **Except as required by law or covered by an exception set forth in the Rule**
- Information Blocking Rule
 - 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.

**Also on May 1, 2020: CMS issued a separate rule, applicable to payers.

45 CFR § 171.101—103.

APPLICABILITY DATES/DEADLINES

- Information Blocking provisions originally set to take effect November 2, 2020.
- April 21, 2020 ONC exercised enforcement discretion allowing extra time for implementation due to COVID-19.
- October 29, 2020, Interim Final Rule was issued further adjusting applicability dates.
- Information Blocking rule is now applicable starting April 5, 2021.
- 85 Fed. Reg. 70063 (Nov. 4, 2020)

INFORMATION BLOCKING

- If conducted by Health IT Developer or Health Information Network/Exchange:
- 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)
- If conducted by a 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)

EXAMPLES OF INFO BLOCKING

- Implementing health IT in nonstandard ways that are likely to substantially increase the complexity or burden of accessing, exchanging, or using EHI;
- Implementing health IT in ways that are likely to restrict the access, exchange, or use of EHI with respect to exporting/transitioning complete information sets between health IT systems.
- Inappropriately citing the HIPAA Privacy Rule as a reason to not share information.
- Organization's policies or contractual arrangements prevent or limit information from being shared with patients or their healthcare providers.

3 TYPES OF ACTORS

1. Healthcare providers

- hospital, skilled nursing facility, nursing facility, home health entity, clinic, community mental health center, renal dialysis facility, blood center, ambulatory surgical center, emergency medical services provider, FQHC, group practice, a pharmacist, pharmacy, laboratory, a physician, a practitioner, a provider for Indian Health Services, rural health clinic, a therapist, others?

2. Developers of Certified Health IT

– any individual or entity that **develops or *offers*** certified health IT, other than a health care provider that self-develops health IT for its own use.

- 42 U.S.C. 300jj; 45 CFR § 171.102.

3 TYPES OF ACTORS - CONTD

3. Health information networks or exchanges

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 EHI:

- (1) Among 2+ unaffiliated individuals or entities that are enabled to exchange with each other; and
- (2) That is for a treatment, payment, or health care operations purpose, (per HIPAA) regardless of whether such individuals or entities are subject to HIPAA.

45 CFR § 171.102

ELECTRONIC HEALTH INFORMATION

Means electronic protected health information as defined in 45 CFR 160.103 to the extent that it would be included in a designated record set as defined in 45 CFR 164.501, regardless of whether the group of records are used or maintained by or for a covered entity as defined in 45 CFR 160.103, but EHI shall not include:

- (1) Psychotherapy notes as defined in 45 CFR 164.501; or
- (2) Information compiled in reasonable anticipation of, or for use in, a civil, criminal, or administrative action or proceeding.

EHI – LIMITED SCOPE

- Until October 6, 2022, EHI's scope for purposes of the information blocking definition is limited to that information represented by data classes and elements within the United States Core Data for Interoperability (USCDI).
- https://www.healthit.gov/isa/sites/isa/files/2020-10/USCDI-Version-1-July-2020-Errata-Final_0.pdf

UNITED STATES CORE DATA FOR INTEROPERABILITY (USCDI)

- USCDI adopted as a standard in the ONC Cures Act Final Rule
- Replaces Common Clinical Data Set (CCDS)
- USCDI: a standardized set of health data classes and constituent data elements for nationwide, interoperable health information exchange
 - New Data Classes
 - Allergies/intolerances
 - Clinical notes
 - Provenance
 - Additional elements for patient demographics and vital signs

INFO BLOCKING EXCEPTIONS



EXCEPTIONS INVOLVING NOT FULFILLING REQUEST



1. PREVENTING HARM EXCEPTION

Not info blocking if:

- Actor has reasonable belief that practice will substantially reduce the risk of harm to patient or another natural person, and:
 1. Practice must be no broader than necessary to substantially reduce the risk of harm.
 2. Risk of harm must:
 - Be determined on individual basis by licensed provider with current or prior provider-patient relationship with patient (subject to individual's right to have determination reviewed by healthcare provider per 45 CFR 164.524(a)(4)); or
 - Arise from data that is known or reasonably suspected to be misidentified, mismatched, corrupt due to technical failure, or erroneous for another reason.

(45 CFR 171.201(a)-(c), (e))

PREVENTING HARM EXCEPTION (cont.)

3. Type of harm must be one that would allow a covered entity to deny access under certain HIPAA provisions, i.e.:
 - Patient request info but licensed provider determines that access is **reasonably likely to endanger the life or physical safety** of the patient or another person (see 45 CFR 164.524(a)(3)(i)).
 - Patient or legal rep request info but info refers to another person (other than a provider) and a licensed provider determines that access is reasonably likely to cause **substantial harm** to such other person (see 45 CFR 164.524(a)(3)(ii)).
 - Legal rep requests info but licensed provider determines access is likely to cause **substantial harm** to the patient or another person (see 45 CFR 164.524(a)(3)(iii)).
 - Other legally permissible access but licensed provider determines that access is reasonably likely to **endanger the life or physical safety** of the patient or another person (see 45 CFR 164.524(a)(3)(i)).

(45 CFR 171.201(d))

PREVENTING HARM EXCEPTION (cont.)

4. One of the following is satisfied:
 - a. Practice is consistent with organizational policy that:
 - Written;
 - Based on relevant clinical, technical, and other expertise;
 - Implemented in a consistent and non-discriminatory manner; and
 - Conforms to other requirements of the exception.
 - b. Absent policy, practice based on a determination that is:
 - Based on reasonably known facts and circumstances; and
 - Based on expertise relevant to implementing the practice consistent with requirements of the exception.

(45 CFR 171.201(f))

2. PRIVACY EXCEPTION

Not info blocking if:

- Deny request in order to protect an individual's privacy so long as satisfy one of the following sub-exceptions:
 1. Federal or state law requires denial because precondition not met;
 2. Disclosure is inconsistent with Health IT developer's legally compliant privacy policy;
 3. HIPAA covered entity properly denies access; or
 4. Individual requests that info not be shared.

(45 CFR § 171.202)

➤ To explain further...

PRIVACY EXCEPTION (cont.)

1. Federal or state law preconditions for allowing access have not been satisfied and:
 - Actor’s practice tailored to the law and is applied in consistent, non-discriminatory manner and either:
 - Practice conforms to actor’s written policies and procedures, or
 - Actor documents why the relevant criteria were not met.
 - If action based on absence of patient consent or authorization, actor must:
 - Take reasonable steps to provide consent or authorization form, and
 - Not improperly encourage or induce the individual to withhold consent.

(45 CFR § 171.202(b))

PRIVACY EXCEPTION (cont.)

2. If actor is a health IT developer that is not required to comply with HIPAA but is seeking to protect the individual's privacy interests:
 - The actor's privacy policies must have been disclosed to the individuals and entities before they agreed to use;
 - Actor must implement the practice according to the policies; and
 - Policies must:
 - Comply with federal and state law;
 - Be tailored to specific privacy risk or interest being addressed; and
 - Be implemented in a consistent and non-discriminatory manner.

(45 CFR § 171.202(c))

PRIVACY EXCEPTION (cont.)

3. If actor is covered by HIPAA and individual requests access per HIPAA, actor's practices must comply with 45 CFR 164.524(a)(2).
 - Unreviewable grounds for denial:
 - Info is excepted from the individual's right of access, e.g.,
 - Outside designated record set.
 - Psychotherapy notes.
 - Info prepared in anticipation of litigation.
 - Certain info from correctional facilities.
 - Certain research info.
 - Records subject to federal Privacy Act.
 - Records obtained from other person under promise of confidentiality.

(45 CFR § 171.202(d))

PRIVACY EXCEPTION (cont.)

4. Unless otherwise required by law, actor may deny access if:
 - Individual requests that actor not share the info.
 - Actor cannot use improper encouragement or inducement.
 - Actor documents the request within reasonable time period.
 - Actor's practice implemented in consistent and non-discriminatory manner.
 - Actor may terminate individual's request only if:
 - Individual terminates its request not to share info in writing or orally and, if oral, oral request is documented; or
 - Actor informs individual it is terminating request provided that such termination:
 - Is not effective if it violates federal or state law; and
 - Only applies to info created or received after the actor gave notice to individual.

(45 CFR § 171.202(d))

3. SECURITY EXCEPTION

Not info blocking if:

- Actor's practice intended to protect security of info if certain conditions met:
 1. Practice is directly related to safeguarding confidentiality, integrity and availability of electronic info.
 2. Practice is tailored to specific security threat being addressed.
 3. Practice is implemented in a consistent, non-discriminatory manner.

(45 CFR § 171.203(a)-(c))

SECURITY EXCEPTION (cont.)

4. If actor has an organizational security policy relating to the practice, the policy must:
 - Be in writing;
 - Have been prepared on the basis of, and be directly responsive to, security risks identified and assessed by the actor;
 - Align with one or more applicable consensus-based standards or best practice guidelines; and
 - Provide objective timeframes and other parameters for identifying, responding to, and addressing security incidents.

(45 CFR § 171.203(d))

SECURITY EXCEPTION (cont.)

5. If actor does not have an organizational security policy relating to the practice:
 - The actor must have made a determination in each case based on particularized facts and circumstances; and
 - Determination concludes that:
 - Practice is necessary to mitigate the security risk; and
 - There are no reasonable and appropriate alternatives to the practice that address the security risk that are less likely to interfere with, prevent, or materially discourage access, exchange or use of e-info.

(45 CFR § 171.203(e))

4. INFEASIBILITY EXCEPTION

Not info blocking if:

- Access or sharing is not feasible as shown by:
 1. Actor cannot fulfill request due to uncontrollable event, e.g., disaster, public health emergency, war, strike, telecom interruption, act of civil authority, etc.
 2. Actor cannot segment requested info from other info that cannot be made available by law, individual's request, or to prevent harm.
 3. Actor documents infeasibility due to specified factors, e.g.,
 - Type of info requested;
 - Cost, actor's resources,
 - Whether practice is non-discriminatory.
 - Whether actor owns or has control over relevant technology.

(45 CFR § 171.204(a))

INFEASIBILITY EXCEPTION (cont.)

- If actor denies request due to infeasibility:
 - Actor must provide the requester with written reasons explaining why the request is infeasible **within 10 days** of request.

(45 CFR § 171.204(b))

5. HEALTH IT PERFORMANCE EXCEPTION

Not info blocking if:

- Actor's practice is implemented to maintain or improve health IT performance if satisfy certain requirements:
 1. Maintenance and improvements to health IT.
 2. Assured level of performance
- If actor takes action to prevent harm, actor need only satisfy requirements in § 171.201.
- If actor takes action in response to a security threat, actor need only satisfy § 171.203.

(45 CFR § 171.205)

HEALTH IT PERFORMANCE EXCEPTION (cont.)

1. Health IT is temporarily unavailable or affected:
 - Maintenance implemented for time no longer than necessary;
 - Maintenance implemented in consistent, non-discriminatory manner; and
 - If maintenance implemented by health IT developer, health info exchange, or health info network:
 - If maintenance planned, ensure it is consistent with existing service level agreements.
 - If maintenance is not planned, ensure it is consistent with existing service level agreements or agreed by the entity to whom the IT services are supplied.

(45 CFR § 171.205(a))

HEALTH IT PERFORMANCE EXCEPTION (cont.)

2. Actor may take action against third-party application that is negatively impacting health IT performance if action:
 - Not taken longer than necessary to resolve negative impacts;
 - Implemented in consistent and non-discriminatory manner; and
 - Consistent with existing service level agreements, where applicable.

(45 CFR § 171.205(b))

EXCEPTIONS INVOLVING PROCEDURES FOR FULFILLING REQUEST



6. CONTENT AND MANNER

- Actor responds to a request for EHI (content) in the specific manner requested.
- Must meet both “content” and “manner”
 - Content – requested EHI limited to USCDI until October 6, 2022
 - Manner – provide access in “any manner requested”
 - in such case not limited by fees/licensing exception conditions

45 CFR § 171.301.

CONTENT AND MANNER

- Alternative manner: If actor does not fulfill the request in the specific manner requested because
 - Technically unable *or*
 - Cannot reach agreeable terms
 - *Then* Fee/license exceptions criteria apply
- Goal to allow negotiation of “market terms” for very specific requests for information
- Exception did not appear in the proposed rule issued by ONC, but resulted from the comments to the proposed rule to address scope of definition of EHI

7. FEES EXCEPTION

Actor may charge fees, *including fees that result in a reasonable profit margin*, for accessing, exchanging or using EHI, such fees may not constitute information blocking provided the fees:

- (1) are based on appropriate conditions;
- (2) not be based on inappropriate conditions; and
- (3) do not include any specifically excluded fees.

45 CFR § 171.302

FEES EXCEPTION

- To qualify for this exception, fees must meet *all* the following conditions:
 - be based on objective and verifiable criteria that are uniformly applied for all similarly situated requestors;
 - be reasonably related to the actor's costs of providing the access, exchange, or use of EHI;
 - be reasonably allocated among all similarly situated persons or entities to whom the technology or service is supplied, or for whom the technology is supported; and
 - be based on costs not otherwise recovered for the same instance of service to a provider and third party.

FEES EXCEPTION

- To qualify for this exception, fees must not be based on any of the following inappropriate conditions:
 - whether the requestor or other person is a competitor, potential competitor, or will be using the electronic health information in a way that facilitates competition with the actor;
 - sales, profit, revenue, or other value that the requestor or other persons derive from the EHI;
 - costs the actor incurred due to the health IT being designed or implemented in a non-standard way (unless the requestor agreed to the fee associated with the non-standard design or implementation to access, exchange, or use the electronic health information);

FEES EXCEPTION

- Inappropriate conditions, contd.
 - costs associated with intangible assets other than their actual development or acquisition costs;
 - opportunity costs unrelated to the access, exchange, or use of electronic health information; or
 - any costs for development of the IP that the actor included in its licensing royalty for that IP pursuant the Licensing Exception described below. In other words, an actor cannot recover its costs for development twice.

FEES EXCEPTION

- Finally, the exception may not be invoked to protect against claims of information blocking if the fee is:
 - a fee charged to a patient for a request of his or her protected health information (“PHI”)(See 45 CFR 164.524(c)(4));
 - a fee *based in any part* on the electronic access by an individual, their personal representative, or another person or entity designated by the individual to access the individual’s EHI; or
 - a fee to perform an export of EHI via the capability of certified health IT for the purposes of switching health IT or to provide patients their EHI; and
 - a fee to export or convert data from an EHR technology that was not agreed to in writing at the time the technology was acquired.

8. LICENSING EXCEPTION

An actor's practice to license interoperability elements for EHI to be accessed, exchanged, or used will not be considered information blocking when the practice meets all of the following conditions:

- Terms of the license must be reasonable and non-discriminatory, and the license royalties charged must meet the criteria outlined below, with consideration of the outlined factors of reasonableness consistent with case law.

45 CFR § 171.303

LICENSING EXCEPTION

- The conditions of the license meet the following conditions:
 - The resulting license includes a scope of rights necessary to: enable the access, exchange or use of the EHI and achieve the intended access via the interoperability element(s).
 - “reasonable royalty” charged that is non-discriminatory, based solely on the independent value of the actor’s technology to the licensee’s products (not on value derived from the actor’s control over essential means of accessing, exchanging, or using EHI);
 - if an actor has licensed the interoperability element through a standards-developing organization, the royalty consistent with those policies; and
 - no royalty for IP is allowable if the actor recovered any of those costs through the Fee exception described above.

LICENSING EXCEPTION

- the licensing terms must be non-discriminatory and comply with the following:
 - Based on objective and verifiable criteria that are uniformly applied for all similarly situated classes of persons and requests.
 - The terms must not be based on whether the requestor or other person is a competitor, potential competitor, or whether the use of EHI may facilitate competition with the actor *or* the revenue or other value the actor may derive from access, exchange, or use of EHI.
- The actor begins to negotiate a license within ten business days from receipt of the request and completes the negotiation within thirty business days.

LICENSING EXCEPTION

- Finally, the actor must not require the licensee to agree to:
 - not compete with the actor;
 - deal exclusively with the actor;
 - obtain additional licenses, products or services that are not related to or can be unbundled from the requested interoperability elements;
 - license, grant, assign, or transfer to the actor any IP of the licensee;
 - pay any fee other than the “reasonable royalty” described above.
- The actor may, however, require a reasonable non-disclosure agreement that is no broader than necessary to prevent unauthorized disclosure of the actor’s trade secrets, so long as:
 - the agreement states with particularity all information the actor claims as trade secrets, and such information meets the definition of trade secret under applicable law.

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>).

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
- Identify and educate stakeholders.
 - Administration, technology, information systems, medical records, compliance, contracting, marketing, etc.



NEXT STEPS

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

HTTPS://WWW.HEALTHIT.GOV/CURESRULE/RESOURCES/INFORMATION-BLOCKING-FAQS

The screenshot shows a web browser window with the URL [healthit.gov/curerule/resources/information-blocking-faqs](https://www.healthit.gov/curerule/resources/information-blocking-faqs). The page header includes the ONC's Cures Act Final Rule logo and navigation links for HealthIT.gov, Email Updates, and View Final Rules. A main navigation bar contains links for Overview, What It Means for Me, Final Rule Policy, and Resources. The breadcrumb trail is Home > Resources > Information Blocking FAQs. A left sidebar lists various content types: Overview, What It Means for Me, Final Rule Policy, Resources (with sub-links for Fact Sheets, Webinars, Media/Press, Blog Posts, and View Final Rules), and Information Blocking FAQs (highlighted). The main content area features a 'Filter by Tags' dropdown menu currently set to '- None -', with 'Filter' and 'Reset' buttons. Below this is the section title 'Information Blocking - General' and a list of two FAQ items, each with a plus sign to expand it. The first FAQ asks: 'Q: 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? *1/15/2021*'. The second FAQ asks: 'Q: What are the applicability and enforcement dates for the information blocking regulations?'.