

HHS Information Blocking Rule: The 8 Exceptions

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Two years ago, the U.S. Department of Health and Human Services (HHS) Office of the National Coordinator (ONC) issued regulations under the 21st Century Cures Act advancing the interoperability of electronic health information (EHI) and access to EHI by patients and interested stakeholders. These regulations (known as the ONC Cures Act "Information Blocking Rule") established conditions under which providers, developers of certified health IT, and health information networks and exchanges cannot knowingly engage in practices likely to interfere with the access, exchange, or use of electronic health information.

ONC will evaluate information blocking claims by reviewing the unique circumstances surrounding the practice and evaluating the following elements to determine whether information blocking has occurred:

- The information involved meets the definition of EHI;
- The Individual or entity engaged in the practice is a regulated Actor;
- The Actor meets the applicable knowledge standard required for that type of Actor;
- The practice is likely to prevent, materially discourage, or inhibit the access, exchange, or use of EHI;
- The practice is required by law; and
- An Information Blocking Rule exception covers the practice.

In the Information Blocking Rule, ONC established eight categories of reasonable and necessary practices that will not be considered information blocking. Failure to meet an exception does not necessarily mean a practice is information blocking. Outside these exceptions, HHS will consider the facts and circumstances surrounding information blocking claims on a case-by-case basis to determine whether the practice rises to the level of an interference and whether the Actor acted with the requisite intent. ONC encouraged Actors to voluntarily comply with an exception so that their practices are not subject to information blocking claims.

The following checklist is excerpted from portions of the Information Blocking Rule, but in no way should be a substitute for an attorney, the regulatory references (e.g., the statute, the Information Blocking Rule, and HHS interpretive guidance), or an analysis of the practice and the Actor's intent.

For legal advice concerning a specific legal question or to review a particular fact situation, please contact your healthcare lawyer.

INFORMATION BLOCKING under the [21st Century Cures Act](#) refers to a practice (an act or an omission) by healthcare providers, health IT developers of certified health IT (Health IT Developer), health information exchanges or health information networks (HIEs or HINs) (each an "Actor") that interferes with the access, exchange, or use of electronic health information (EHI),¹ unless the practice is required by law or covered by an Information Blocking exception.

Access: The ability or means necessary to make EHI available for exchange or use

Exchange: The ability of EHI to be transmitted between and among different technologies, systems, platforms, or networks

Use: The ability for EHI, once accessed or exchanged, to be understood and acted upon.

Under the [HHS Information Blocking Rule](#), an Actor is subject to an Information Blocking claim if:

1. A health IT developer, HIN or HIE, and the health IT developer, HIN or HIE **knows, or should know**, that the practice is likely to interfere with access, exchange, or use of EHI

Health IT developer of certified health IT ("Health IT Developer") – someone (other than a healthcare provider that self-develops health IT for its own use) that (1) *develops or offers* health IT, and (2) has, at the time it engages in the practice, one or more health IT modules certified under the ONC Health IT Certification Program.

HIN or HIE – someone 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 more than two unaffiliated individuals or entities (other than the one to whom this definition might apply) that are enabled to exchange with each other; and (2) that is for a Treatment, Payment, or Health Care Operations purpose under HIPAA (regardless of whether the individuals or entities are subject to HIPAA).

2. A healthcare provider (not acting in the capacity of a health IT developer, HIN, or HIE), who **knows that the practice is unreasonable and** likely to interfere with access, exchange, or use of EHI.

¹ EHI is Individually identifiable health information maintained in or transmitted by electronic media but is limited to the extent it would be considered [a designated record set under HIPAA](#) (regardless of whether used or maintained by or for a HIPAA covered entity) and for the period before October 6, 2022, to only the data elements in the [United States Core Data for Interoperability \(USCDI v.1\)](#), a standardized set of health data classes and constituent data elements for exchanging health information.

ANALYSIS: An Information Blocking claim may be brought for any legally permissible practice that does not meet an Information Blocking Rule exception if the Actor knew (or for health IT developers, HINs or HIEs, should have known) that the practice was likely to interfere with the access, exchange or use of EHI.

Conversely, an Actor's practice that is likely to be an interference with the access, exchange, or use of EHI is not treated as Information Blocking if the practice is either:

- (1) done **without the knowledge** required of the Actor,
- (2) **required by law**, OR
- (3) meets all applicable requirements and conditions of at least one of the following **Information Blocking Rule exceptions** at all relevant times.

ONC divided the exceptions for requests to access, exchange or use of EHI into two categories: those requests that are not fulfilled and procedures for those requests that would be fulfilled.

INFORMATION BLOCKING RULE EXCEPTIONS - Information Blocking Rule Exceptions that Involve Not Fulfilling Requests To Access, Exchange, or Use EHI

§ 171.201 Preventing Harm Exception: When will an Actor's practice that is likely to interfere with the access, exchange, or use of EHI in order to prevent harm not be considered Information Blocking?

An Actor's practice that is likely to interfere with the access, exchange, or use of EHI in order to prevent harm will not be considered Information Blocking if:

- the practice meets the conditions in paragraphs (a) and (b) below,
- satisfies at least one condition from (c), (d), and (f) below, and
- meets the condition in paragraph (e) below if applicable.

(a) **Reasonable belief.** The Actor engaging in the practice must hold a reasonable belief that the practice will substantially reduce a risk of harm to the patient² who is the subject of the EHI or another natural person that would otherwise arise from the access, exchange, or use of EHI affected by the practice.

(b) **Practice breadth.** The practice must be no broader than necessary to substantially reduce the risk of harm that the practice is implemented to reduce.

(c) **Type of risk³.** The risk of harm must either:

- (1) *Individualized Determination:* Be determined on an individualized basis in the exercise of professional judgment by a licensed healthcare professional who has a current or prior clinician-patient relationship with the patient whose EHI is affected by the determination; or
- (2) *Corrupted Data:* Arise from data known or reasonably suspected to be misidentified or mismatched, corrupt due to technical failure, or erroneous for another reason.

(d) **Type of harm.** The type of harm must be one that could serve as one of the reviewable grounds under the HIPAA Privacy Rule for a HIPAA covered entity to deny access to an Individual's PHI:

- (1) *Reasonably likely to cause substantial harm to a personal representative* under HIPAA §164.524(a)(3)(iii) if the practice is likely to, or in fact does, interfere with access, exchange, or use (as defined in the Information Blocking Rule) of the patient's EHI by their legal representative (including but not limited to personal representatives under 45 CFR 164.502), and the practice is implemented pursuant to an individualized determination of risk of harm consistent with paragraph (c)(1) of this section;
- (2) *Reasonably likely to cause substantial harm to another person* referred to in the PHI under HIPAA §164.524(a)(3)(ii) if the practice is likely to, or in fact does, interfere with the patient's or their legal representative's access to use or exchange (as defined in the Information Blocking Rule) of information that references another natural person and the practice is implemented pursuant to an individualized determination of risk of harm consistent with paragraph (c)(1) of this section;
- (3) *Reasonably likely to endanger the life or physical safety of the Individual* under HIPAA §164.524(a)(3)(i) if the practice is likely to, or in fact does, interfere with the patient's access, exchange, or use (as defined in the Information Blocking Rule) of their own EHI, *regardless of* whether the (type of) risk of harm that the practice is implemented to substantially reduce is consistent with paragraph (c)(1) or (2) of this section; or

² Here a "patient" is a natural person who is the subject of the EHI affected by the Actor's practice.

³ See page 5 for an ONC chart outlining the types of harm recognized under an individualized determination.

(4) *Reasonably likely to endanger the life or physical safety of another person* under HIPAA §164.524(a)(3)(i) if the practice is likely to, or in fact does, interfere with a legally permissible access, exchange, or use (as defined in the Information Blocking Rule) of EHI not described in paragraph (d)(1), (2), or (3) of this section, and *regardless of* whether the (type of) risk of harm the practice is implemented to substantially reduce is consistent with paragraph (c)(1) or (2) of this section.

(e) **Patient right to request review of an individualized determination of risk of harm.** If the risk of harm is consistent with an individualized determination under paragraph (c)(1) of this section, the Actor must implement the practice in a manner consistent with any rights the Individual patient whose EHI is affected may have (for a review of the denial by a licensed healthcare professional) under §164.524(a)(4), or any federal, state, or tribal law, to have the determination reviewed and potentially reversed.

(f) **Practice implemented based on an organizational policy or a determination specific to the facts and circumstances.** The practice must be consistent with an organizational policy that meets paragraph (f)(1) of this section or, in the absence of an organizational policy applicable to the practice or to its use in particular circumstances, the practice must be based on a determination that meets paragraph (f)(2) of this section.

(1) **An organizational policy on preventing harm** must:

- (i) Be in writing;
- (ii) Be based on relevant clinical, technical, and other appropriate expertise;
- (iii) Be implemented in a consistent and non-discriminatory manner; and
- (iv) Conform each practice to the conditions in paragraphs (a) and (b) of this section, as well as the conditions in paragraphs (c) through (e) of this section as applicable to the practice and its use.

(2) **Or a preventing harm determination** must:

- (i) Be based on facts and circumstances known or reasonably believed by the Actor at the time the determination was made and while the practice remains in use; and
- (ii) Be based on expertise relevant to implementing the practice consistent with the conditions in paragraphs (a) and (b) of this section, as well as the conditions in paragraphs (c) through (e) of this section applicable to the practice and its use in particular circumstances.

ONC Preventing Harm Exception: Types of Harm Recognized under an Individualized Analysis⁴

Access, exchange, or use of patient's EHI ¹	EHI for which access, exchange, or use is affected by the interfering practice is	Applicable type of harm	Regulation Text References
Patient exercising own right of access	Patient's EHI	Danger to life or physical safety of the patient or another person	§ 171.201(d)(3), referencing HIPAA Privacy Rule § 164.524(a)(3)(i)
	Patient's EHI that references another person	Substantial harm ³ to such other person	§ 171.201(d)(2), referencing HIPAA Privacy Rule § 164.524(a)(3)(ii)
Patient's personal representative as defined in HIPAA Privacy Rule (45 CFR 164.502) exercising right of access to patient's EHI (for example, parent of a minor child) ²	Patient's EHI	Substantial harm ³ to the patient or to another person	§ 171.201(d)(1), referencing HIPAA Privacy Rule § 164.524(a)(3)(iii)
	Patient's EHI that references another person	Substantial harm ³ to such other person	§ 171.201(d)(2), referencing HIPAA Privacy Rule § 45 CFR 164.524(a)(3)(ii) ⁴

1 For simplicity of presentation, this table focuses only on patient access use case examples where risk has been determined on an individual basis (45 CFR 171.201(c)(1)). Where the risk arises from data that is known or reasonably suspected to be misidentified or mismatched, corrupt due to technical failure, or erroneous for another reason (45 CFR 171.201(c)(2)), the exception's applicable **type of harm** conditions (45 CFR 171.201(d)(3) and (4)) recognize only danger to life or physical safety of the patient or another person.

2 For more information about the definition of a "personal representative" under the HIPAA Privacy Rule, please see <https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/personal-representatives/index.html>

3 "Substantial harm" includes "substantial physical, emotional, or psychological harm" (see, for example, HIPAA Privacy Rule preamble at 65 FR 82556).

4 In order for the Preventing Harm Exception to cover any practice likely to interfere with access, exchange, or use of EHI based on an individualized (45 CFR 171.201(c)(1)) determination of risk, the practice must also satisfy requirements in 45 CFR 171.201(a), (b), (e), and (f).

4 From [ONC website](#) (last viewed 6.7.22).

§ 171.202 Privacy Exception: When will an Actor's practice of not fulfilling a request to access, exchange, or use EHI in order to protect an Individual's privacy not be considered Information Blocking?

An Actor's practice that is likely to interfere with the access, exchange, or use of EHI in order to protect an Individual's privacy of EHI will not be considered Information Blocking when the practice meets all of the requirements of at least one sub-exception in (b) through (e) of this section.

(a) **See definition of Individual in this section**⁵

(b) **Privacy Sub-exception 1 – A legal precondition is not satisfied.** To qualify for the exception on the basis that state or federal law requires one or more preconditions for providing access, exchange, or use of EHI that have not been satisfied, the following requirements must be met:

(1) The Actor's practice is tailored to the applicable precondition not satisfied, is implemented in a consistent and non-discriminatory manner, and either:

(i) Conforms to the Actor's organizational policies and procedures that:

(A) Are in writing;

(B) Specify the criteria to be used by the Actor to determine when the precondition would be satisfied and, as applicable, the steps that the Actor will take to satisfy the precondition; and

(C) Are implemented by the Actor, including by providing training on the policies and procedures; or

(ii) Are documented by the Actor, on a case-by-case basis, identifying the criteria used by the Actor to determine when the precondition would be satisfied, any criteria that were not met, and the reason why the criteria were not met.

(2) If the precondition relies on the provision of a consent or authorization from an Individual and the Actor has received a version of such a consent or authorization that does not satisfy all elements of the precondition required under applicable law, the Actor must:

(i) Use reasonable efforts within its control to provide the Individual with a consent or authorization form that satisfies all required elements of the precondition or provide other reasonable assistance to the Individual to satisfy all required elements of the precondition; and

(ii) Not improperly encourage or induce the Individual to withhold the consent or authorization.

(3) For purposes of determining whether the Actor's privacy policies and procedures and actions satisfy the requirements of paragraphs (b)(1)(i) and (b)(2) above when the Actor's operations are subject to multiple laws that have inconsistent preconditions, they shall be deemed to satisfy the requirements of the paragraphs if the Actor has adopted uniform privacy policies and procedures to address the more restrictive preconditions.

(c) **Privacy Sub-exception 2 – Health IT developer is not covered by HIPAA.** If the Actor is a health IT developer that is not required to comply with the HIPAA Privacy Rule, when engaging in a practice that promotes the privacy interests of an Individual, the Actor's organizational privacy policies must have been disclosed to the Individuals and entities that use the Actor's product or service before they agreed to use them, and must implement the practice according to a process described in the organizational privacy policies. The Actor's organizational privacy policies must:

(1) Comply with state and federal laws, as applicable;

(2) Be tailored to the specific privacy risk or interest being addressed; **and**

(3) Be implemented in a consistent and non-discriminatory manner.

⁵ In this Section, *Individual* means one or more of the following:

(i) the person who is the subject of PHI;

(ii) any other natural person who is the subject of the EHI being accessed, exchanged, or used;

(iii) a person who legally acts on behalf of a person described in paragraph (a)(1) or (2) of this section in making decisions related to healthcare as a personal representative, in accordance with the [HIPAA Privacy Rule standards for a personal representative](#);

(iv) a person who is a legal representative of and can make healthcare decisions on behalf of any person described in paragraph (a)(1) or (2) of this section, or

(v) an executor, administrator, or other person having authority to act on behalf of a deceased person described in paragraph (a)(1) or (2) of this section or the Individual's estate under State or other law.

- (d) **Privacy Sub-exception 3 – Denial of an Individual’s request for their EHI consistent with the HIPAA Access and Unreviewable Grounds for Denial Standards.** If an Individual requests EHI under the right of access provision under [45 CFR 164.524\(a\)\(1\)](#) from an Actor that must comply with that provision, the Actor’s practice must be consistent with the HIPAA Privacy Rule reviewable grounds for denial at [45 CFR 164.524\(a\)\(2\)](#).
- (e) **Privacy Sub-exception 4 – Respecting an Individual’s request not to share information.** Unless otherwise required by law, an Actor may elect not to provide access, exchange, or use of an Individual’s EHI if the following requirements are met:
- (1) The Individual requests that the Actor not provide such access, exchange, or use of EHI without any improper encouragement or inducement of the request by the Actor;
 - (2) The Actor documents the request within a reasonable time period;
 - (3) The Actor’s practice is implemented in a consistent and non- discriminatory manner; **and**
 - (4) An Actor may terminate an Individual’s request for a restriction to not provide such access, exchange, or use of the Individual’s EHI only if:
 - (i) The Individual agrees to the termination in writing or requests the termination in writing;
 - (ii) The Individual orally agrees to the termination and the oral agreement is documented by the Actor; or
 - (iii) The Actor informs the Individual that it is terminating its agreement to not provide such access, exchange, or use of the Individual’s EHI except that such termination is:
 - (A) Not effective to the extent prohibited by applicable federal or state law; and
 - (B) Only applicable to EHI created or received after the Actor has so informed the Individual of the termination.

IB Exceptions That Involve Not Fulfilling Requests to Access, Exchange, or Use EHI

§ 171.203 Security Exception: When will an Actor’s practice that is likely to interfere with the access, exchange, or use of EHI in order to protect the security of EHI not be considered Information Blocking?

An Actor’s practice that is likely to interfere with the access, exchange, or use of EHI in order to protect the security of EHI will not be considered Information Blocking when the practice:

- meets the conditions in paragraphs (a), (b), and (c) of this section, and
 - meets either the condition in paragraph (d) of this section or the condition in paragraph (e) of this section.
- (a) The practice must be directly related to safeguarding the confidentiality, integrity, and availability of EHI.
- (b) The practice must be tailored to the specific security risk being addressed.
- (c) The practice must be implemented in a consistent and non-discriminatory manner.

OPTION 1: METHOD FOR ORGANIZATIONAL SECURITY POLICY

- (d) If the practice implements an organizational security policy, the policy must:
- (1) Be in writing;
 - (2) Have been prepared on the basis of, and be directly responsive to, security risks identified and assessed by or on behalf of the Actor;
 - (3) Align with one or more applicable consensus-based standards or best practice guidance; and
 - (4) Provide objective timeframes and other parameters for identifying, responding to, and addressing security incidents.

OPTION 2: THE CASE-BY-CASE DETERMINATION METHOD

(e) If the practice does not implement an organizational security policy, the Actor must have made a determination in each case, based on the particularized facts and circumstances, that:

- (1) The practice is necessary to mitigate the security risk to EHI; and
- (2) There are no reasonable and appropriate alternatives to the practice that address the security risk that are less likely to interfere with the access, exchange or use of EHI.

IB Exceptions That Involve Not Fulfilling Requests to Access, Exchange, or Use EHI

§ 171.204 Infeasibility Exception: When will an Actor's practice of not fulfilling a request to access, exchange, or use EHI due to the infeasibility of the request not be considered Information Blocking?

An Actor's practice of not fulfilling a request to access, exchange, or use EHI due to the infeasibility of the request will not be considered Information Blocking when the practice meets **one of the conditions** in paragraph (a) of this section and responds under (b) *within 10 business days*⁶ of receiving the request.

(a) **Conditions:**

- (1) **OPTION 1: UNCONTROLLABLE EVENTS.** The Actor cannot fulfill the request for access, exchange, or use of EHI due to a natural or human-made disaster, public health emergency, public safety incident, war, terrorist attack, civil insurrection, strike or other labor unrest, telecommunication or internet service interruption, or act of military, civil or regulatory authority.
- (2) OR **OPTION 2: DATA SEGMENTATION.** The Actor cannot fulfill the request for access, exchange, or use of EHI because the Actor cannot unambiguously segment the requested EHI from EHI that:
 - (i) Cannot be made available due to an Individual's preference or because the EHI cannot be made available by law; or
 - (ii) May be withheld under the Information Blocking Preventing Harm Exception at §171.201.
- (3) OR **OPTION 3: INFEASIBLE UNDER THE CIRCUMSTANCES.**
 - (i) The Actor demonstrates, before responding under paragraph (b) below, through a contemporaneous written record or other documentation its consistent and non-discriminatory consideration of the following factors that led to its determination that complying with the request would be infeasible under the circumstances:
 - (A) The type of EHI 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 EHI 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, HIE, or HIN through which EHI is accessed or exchanged; and
 - (F) Why the Actor was unable to provide access, exchange, or use of EHI consistent with the Information Blocking *Content and Manner Exception* at §171.301.
 - (ii) **MAY NOT** consider whether the manner requested would facilitate competition with the Actor or prevent the Actor from charging a fee or result in a reduced fee.

(b) **AND Responding to requests.** If an Actor does not fulfill a request for access, exchange, or use of EHI for any of the reasons provided in paragraph (a) of this section, the Actor must, within ten (10) business days of receipt of the request, provide to the requestor in writing the reason(s) why the request is infeasible.

⁶ Consider the Content and Manner Exception at §171.301 if unable to demonstrate the basis for infeasibility but respond to the requestor with the reasons for not providing USCDI/EHI within 10 business days. Note also that consideration of the Content and Manner Exception is required if relying on Option 3.

IB Exceptions That Involve Not Fulfilling Requests to Access, Exchange, or Use EHI

§ 171.205 Health IT Performance Exception: When will an Actor's practice implemented to maintain or improve health IT performance and likely to interfere with the access, exchange, or use of EHI not be considered Information Blocking?

An Actor's practice that is implemented to maintain or improve health IT performance and that is likely to interfere with the access, exchange, or use of EHI will not be considered Information Blocking when the practice meets a condition in paragraph (a), (b), (c), or (d) of this section, as applicable to the particular practice and the reason for its implementation.

(a) **Maintenance and improvements to health IT.** When an Actor implements a practice that makes health IT under that Actor's control temporarily unavailable, or temporarily degrades the performance of health IT to perform maintenance or improvements to the health IT, the Actor's practice must be:

- (1) Implemented for a period of time no longer than necessary to complete the maintenance or improvements for which the health IT was made unavailable or the health IT's performance degraded;
- (2) Implemented in a consistent and non-discriminatory manner; and
- (3) If the unavailability or degradation is initiated by a health IT developer, HIE, or HIN:
 - (i) *Planned.* Consistent with existing service level agreements between the Individual or entity to whom the health IT developer, HIE, or HIN supplied the health IT; or
 - (ii) *Unplanned.* Consistent with existing service level agreements between the Individual or entity; or agreed to by the Individual or entity to whom the health IT developer, HIE, or HIN supplied the health IT.

(b) **Assured level of performance.** An Actor may take action against third-party applications 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.

(c) **Practices that prevent harm.** If the unavailability of health IT for maintenance or improvements is initiated by an Actor in response to a risk of harm to a patient or another person, the Actor does not need to satisfy the requirements of this section but must comply with all requirements of §171.201 at all relevant times to qualify for an exception.

(d) **Security-related practices.** If the unavailability of health IT for maintenance or improvements is initiated by an Actor in response to a security risk to EHI, the Actor does not need to satisfy the requirements of this section, but must comply with all requirements of the Information Blocking Security Exception at §171.203 at all relevant times to qualify for an exception.

IB Exceptions Involving Procedures for Fulfilling Requests to Access, Exchange, or Use EHI

§ 171.301 Content and Manner Exception: When will an Actor's practice of limiting the content of its response to or the manner in which it fulfills a request to access, exchange, or use EHI not be considered Information Blocking?

An Actor's practice of limiting the content of its response to or the manner in which it fulfills a request to access, exchange, or use EHI will not be considered Information Blocking when the practice meets **both of the following conditions**:

- (a) **The EHI content condition** – An Actor must respond to a request to access, exchange, or use EHI with:
- (1) *USCDI*. For up to October 6, 2022, at a minimum, the EHI identified by the data elements represented in the USCDI v.1 standard adopted in §170.213.
 - (2) *All EHI*. On and after October 6, 2022, EHI as defined in §171.102 (without the USCDI limitation).

AND

- (b) **The Manner condition** – (In the manner requested or when the Actor cannot fulfill in the requested format, an alternative format in priority order):
- (1) **Manner requested.**
 - (i) An Actor must fulfill a request for the applicable EHI content in any manner requested, unless the Actor is technically unable to fulfill the request or cannot reach agreeable terms with the requestor to fulfill the request.
 - (ii) If an Actor fulfills a request for EHI in the manner requested, then:
 - (A) Any fees charged by the Actor in relation to fulfilling the request are not required to satisfy the Information Blocking Fees Exception at §171.302; and
 - (B) Any license of interoperability elements granted by the Actor in relation to fulfilling the request is not required to satisfy the Information Blocking Licensing exception at §171.303.
 - (2) **Alternative manner.** If an Actor does not fulfill a request described under the content condition in paragraph (a) in any manner requested because it either (1) is *technically unable* to fulfill the request (in the manner requested), or (2) cannot *reach agreeable terms* with the requestor to fulfill the request, the Actor must fulfill the request in an alternative manner, as follows:
 - (i) The Actor must fulfill the request **without unnecessary delay** in the **following order of priority**, starting with paragraph (b)(2)(i)(A) of this section and *only proceeding to the next consecutive paragraph if the Actor is technically unable to fulfill* the request in the manner identified in a paragraph.
 - (A) **Certified technology:** Using technology certified to standard(s) adopted in part 170 that is specified by the requestor (e.g., HL7 FHIR API).
 - (B) **Other Standards/Interoperable Format:** Using content and transport standards *specified by the requestor* and published by (1) the federal government or (2) an American National Standards Institute (ANSI) accredited standards developing organization.
 - (C) **Machine-readable format**, including the means to interpret the EHI⁷, *agreed upon with the requestor* (e.g., CSV, public domain standards, public advisory).
 - (ii) Any fees charged by the Actor to fulfill the request must satisfy the Fees Exception at §171.302.
 - (iii) Any license of interoperability elements granted by the Actor to fulfill the request must satisfy the License Exception at §171.303.

⁷ The NIST test for machine readable: Can the information be consumed by another software program using consistent logic? See also [ONC FAQ 411.2021Nov](#) (regarding machine readable PDFs).

IB Exceptions Involving Procedures for Fulfilling Requests to Access, Exchange, or Use EHI

§ 171.302 Fees Exception: When will an Actor's practice of charging fees for accessing, exchanging, or using EHI not be considered Information Blocking?

An Actor's practice of charging fees, including fees that result in a reasonable profit margin, for accessing, exchanging, or using EHI will not be considered Information Blocking when the practice:

- meets the conditions in paragraph (a) of this section;
 - does not include any of the excluded fees in paragraph (b) of this section; and
 - as applicable, meets the condition in paragraph (c) of this section.
- (a) **Basis for fees condition.**
- (1) The fees an Actor charges must be:
 - (i) Based on objective and verifiable criteria that are uniformly applied for all similarly situated classes of persons or entities and requests;
 - (ii) Reasonably related to the Actor's costs of providing the type of access, exchange, or use of EHI to, or at the request of, the person or entity to whom the fee is charged;
 - (iii) 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
 - (iv) Based on costs not otherwise recovered for the same instance of service to a provider and third party.
 - (2) The fees an Actor charges **must not be based on:**
 - (i) Whether the requestor or other person is a competitor, potential competitor, or will be using the EHI in a way that facilitates competition with the Actor;
 - (ii) Sales, profit, revenue, or other value that the requestor or other persons derive or may derive from the access, exchange, or use of the EHI;
 - (iii) 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 of the EHI;
 - (iv) Costs associated with intangible assets other than the actual development or acquisition costs of such assets;
 - (v) Opportunity costs unrelated to the access, exchange, or use of EHI; or
 - (vi) Any costs that led to the creation of intellectual property, if the Actor charged a royalty for that intellectual property pursuant to the Information Blocking Licensing Exception at §171.303 and that royalty included the development costs for the creation of the intellectual property.
- (b) **Excluded fees condition.** This exception *does not apply* to any of the following:
- (1) A fee prohibited by the HIPAA Privacy Rule at [45 CFR 164.524\(c\)\(4\)](#);
 - (2) A fee based in any part on the electronic access of an Individual's EHI by the Individual, their personal representative, or another person or entity designated by the Individual. *Electronic access* means an internet-based method that makes EHI available at the time the EHI is requested and where no manual effort is required to fulfill the request.
 - (3) 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
 - (4) 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.
- (c) **Compliance with the conditions of certification condition.** Notwithstanding any other provision of this exception, if the Actor is a health IT developer subject to the ONC Conditions of Certification for Assurances at [§170.402\(a\)\(4\)](#), and the EHI Export Criterion at [§170.404](#), or both of this subchapter, the Actor must comply with all requirements of such conditions for all practices and at all relevant times.

IB Exceptions Involving Procedures for Fulfilling Requests to Access, Exchange, or Use EHI

§ 171.303 Licensing Exception: When will an Actor's practice to license interoperability elements in order for EHI to be accessed, exchanged, or used not be considered Information Blocking?

An Actor's practice to license interoperability elements⁸ for EHI to be accessed, exchanged, or used will not be considered Information Blocking when the practice meets **all of the following conditions**.

(a) **Negotiating a license conditions.** Upon receiving a request to license an interoperability element for the access, exchange, or use of EHI, the Actor must:

- (1) Begin license negotiations with the requestor within 10 business days from receipt of the request; and
- (2) Negotiate a license with the requestor, subject to the licensing conditions in paragraph (b) of this section, within 30 business days from receipt of the request.

(b) **Licensing conditions.** The license provided for the interoperability element(s) needed to access, exchange, or use EHI must meet the following conditions:

- (1) **Scope of rights.** The license must provide all rights necessary to:
 - (i) Enable the access, exchange, or use of EHI; and
 - (ii) Achieve the intended access, exchange, or use of EHI via the interoperability element(s).
- (2) **Reasonable royalty.** If the Actor charges a royalty for the use of the interoperability elements described in paragraph (a) of this section, the royalty must be reasonable and comply with the following requirements:
 - (i) The royalty must be non-discriminatory, consistent with paragraph (b)(3) of this section.
 - (ii) The royalty must be based solely on the independent value of the Actor's technology to the licensee's products, not on any strategic value stemming from the Actor's control over essential means of accessing, exchanging, or using EHI.
 - (iii) If the Actor has licensed the interoperability element through a standards developing organization in accordance with such organization's policies regarding the licensing of standards-essential technologies on terms consistent with those in this exception, the Actor may charge a royalty that is consistent with such policies.
 - (iv) An Actor may not charge a royalty for intellectual property if the Actor recovered any development costs pursuant to the Information Blocking Fees Exception at §171.302 that led to the creation of the intellectual property.
- (3) **Non-discriminatory terms.** The terms (including royalty terms) on which the Actor licenses and otherwise provides the interoperability elements **must be non-discriminatory** and comply with the **following** requirements:
 - (i) The terms must be based on objective and verifiable criteria that are uniformly applied for all similarly situated classes of persons and requests.
 - (ii) The terms must not be based in any part on:
 - (A) Whether the requestor or other person is a competitor, potential competitor, or will be using EHI obtained via the interoperability elements in a way that facilitates competition with the Actor; or
 - (B) The revenue or other value the requestor may derive from access, exchange, or use of EHI obtained via the interoperability elements.

⁸ Interoperability element means hardware, software, integrated technologies or related licenses, technical information, privileges, rights, intellectual property, upgrades, or services that may be necessary to access, exchange, or use EHI; and is controlled by the Actor, which includes the ability to confer all rights and authorizations necessary to use the element to enable the access, exchange, or use of EHI.

- (4) **Collateral terms.** The Actor must not require the licensee or its agents or contractors to do, or to agree to do, any of the following:
- (i) Not compete with the Actor in any product, service, or market.
 - (ii) Deal exclusively with the Actor in any product, service, or market.
 - (iii) Obtain additional licenses, products, or services that are not related to or can be unbundled from the requested interoperability elements.
 - (iv) License, grant, assign, or transfer to the Actor any intellectual property of the licensee.
 - (v) Pay a fee of any kind whatsoever, except as described in paragraph (b)(2) of this section, unless the practice meets the requirements of the exception in Information Blocking Fees Exception at §171.302.
- (5) **Non-disclosure agreement.** The Actor **may require** a reasonable non-disclosure agreement that is no broader than necessary to prevent unauthorized disclosure of the Actor's trade secrets, provided:
- (i) The agreement states with particularity all information the Actor claims as trade secrets; and
 - (ii) Such information meets the definition of a trade secret under applicable law.
- (c) **Additional conditions relating to the provision of interoperability elements.** The Actor **must not** engage in any practice that has **any of the following** purposes or effects.
- (1) Impeding the efficient use of the interoperability elements to access, exchange, or use EHI for any permissible purpose (i.e., any purpose for which a person is authorized, permitted, or required to access, exchange, or use EHI under applicable law).
 - (2) Impeding the efficient development, distribution, deployment, or use of an interoperable product or service for which there is actual or potential demand.
 - (3) Degrading the performance or interoperability of the licensee's products or services, unless necessary to improve the Actor's technology and after affording the licensee a reasonable opportunity to update its technology to maintain interoperability.

For legal advice concerning a specific legal question or to review a particular fact situation, please contact your healthcare lawyer.



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