

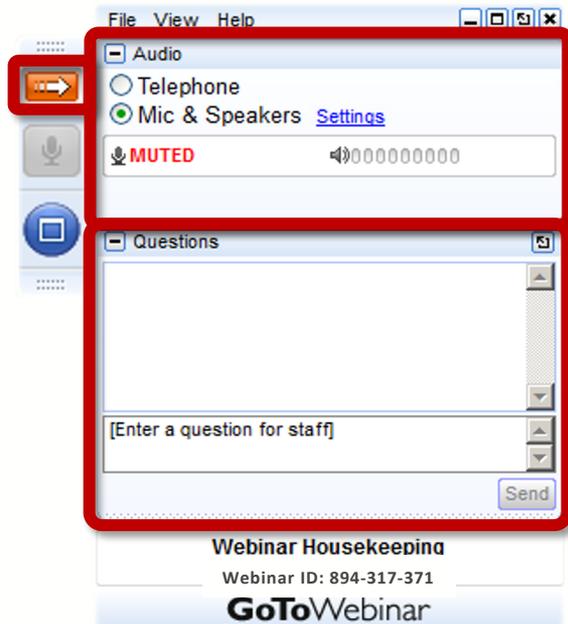


Information Blocking Compliance Bootcamp

Session 4: What are Information Blocking Exceptions and How Should I Use Them: Part 2?

March 3, 2021

How To Participate Today



Your Participation

Open and close your control panel

Join audio:

- Choose "Mic & Speakers" to use VoIP
- Choose "Telephone" and dial using the information provided

Submit questions and comments via the Questions panel

Note: Today's presentation is being recorded and will be provided

Problems or Questions? Contact the Interoperability Matters Team at:

interopmatters@sequoiaproject.org

Meet The Sequoia Project Team



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About the Sequoia Project

The Sequoia Project is the independent, trusted advocate for nationwide health information exchange. In the public interest we steward current programs, incubate new initiatives, each with their own mission, governance, membership and structure, and educate our community.



SECURE



INTEROPERABLE



NATIONWIDE

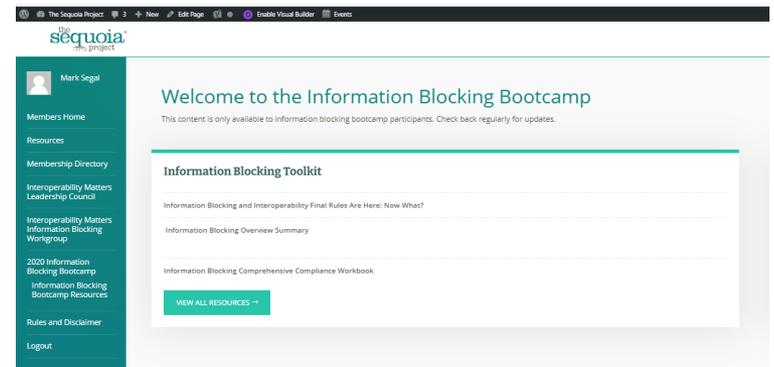
Information Blocking Compliance Boot Camp Sessions

- | | |
|---|-------------------|
| ✓ Information Blocking Overview | January 20, 2021 |
| ✓ Violating the Information Blocking Rule | February 3, 2021 |
| ✓ Exceptions: Part 1 | February 17, 2021 |
| 4. Exceptions: Part 2 | March 3, 2021 |
| 5. Enforcement Issues | March 17, 2021 |
| 6. Compliance: Part 1 | March 31, 2021 |
| 7. Compliance: Part 2 and Wrap-Up | April 14, 2021 |

Bootcamp Materials

We have developed materials for you to use as part of the Bootcamp. These supplement, but do not replace, Bootcamp sessions.

- *Information Blocking Summary*—an extensive narrative that provides a comprehensive discussion of:
 - The legal authority for Information Blocking in the CURES Act, the ONC Final Rule, and the OIG Proposed Rule;
 - Key definitions and the exceptions.
- *Compliance Planning Workbook*—a comprehensive discussion of how to approach organizational compliance and implementation for Information Blocking with checklists, examples and suggestions.



<https://sequoiaproject.org/2021-information-blocking-bootcamp/>

Certificate of Participation

- Sequoia has invested extensive resources into this Bootcamp to provide participants with an excellent orientation to Information Blocking
- The core faculty, Steve Gravely and Mark Segal, are experts on the Information Blocking provisions
- The written materials have been carefully vetted for accuracy and objectivity
- Each session will include vital information and time for group discussion
- Participants are encouraged to share ideas and information outside of the bootcamp sessions
- All participants that attend each bootcamp session will receive a **Certificate of Completion** as tangible evidence of their achievement



Information Blocking Compliance Boot Camp: Office Hours

Between 3pm and 4pm ET on the following dates:

- ✓ January 27, 2021
- ✓ February 10, 2021
- ✓ February 24, 2021
- 4. March 10, 2021
- 5. March 24, 2021
- 6. April 7, 2021
- 7. April 21, 2021

Quick Refresher-Exceptions Overview and Part 1

- “Exception” is term in ONC Information Blocking Rule definition
- It is used to implement the Cures directive to ONC to identify activities that are “reasonable and necessary” despite the likelihood that the practice would be information blocking
- Many documentation requirements are embedded in exception conditions; documentation of how conditions are met is essential
- Failing to meet an exception does not mean a practice is information blocking, only that it would not have guaranteed protection from CMPs or disincentives, and would be evaluated on case-by-case basis
- With this context, we reviewed the Preventing Harm, Privacy, Security, and Health IT Performance Exceptions



Session 4: Exceptions – Part 2

Session Goals

- This session will continue with a closer look at the exceptions
- We will make a detailed review of the remaining exceptions: including Content and Manner, Fees, Licensing, and Infeasibility
- We'll also address interactions and sequencing of exceptions

Content and Manner Exception (1)

New “gateway” exception in the Final Rule, addressing concerns in the public comments to the Proposed Rule about the broad definition of EHI and the Infeasibility Exception

If an Actor does not fulfill a request for EHI with the content requested in the manner requested, the Actor must meet two conditions:

- 1. Content condition**—An actor must respond to requests to access, exchange, or use electronic health information with:
 - EHI in **USCDI data elements through October 5, 2022**; and
 - **On and after October 6, 2022, all EHI** as (re)defined in [§ 171.102](#)
- ONC revised the EHI definition in the Final Rule to align with HIPAA ePHI definition
 - There is no flexibility here: you must provide EHI as defined in the Final Rule (for the applicable time period)
- In addition to the Content condition . . .

Content and Manner Exception (2)

2. *Manner condition*

- (i) The Actor **must** fulfill request for EHI **in any manner requested, unless the Actor is technically unable to comply OR the Actor cannot reach terms with requestor**
 - “Technically unable” means that the Actor cannot comply due to technical limitations with its systems (e.g., request via API and Actor cannot use API)
 - ONC stresses this is a very high bar and does NOT include an Actor’s preference to fulfill differently due to cost, burden or similar reason
- (ii) **If the Actor fulfills such request in any manner requested:**
 - Any fees charged in fulfilling the response *need not* satisfy Fee Exception (i.e., fees could be “market rate”); and
 - Any license of interoperability elements granted in fulfilling the request *need not* satisfy the Licensing Exception
- ONC provides an alternative if the Actor cannot do the above . . .

Content and Manner Exception (3)

- **Alternative manner. If the Actor does not fulfill the request in *any manner requested* because technically unable or cannot reach terms with requestor (intended as a high bar), the Actor must fulfill the request in an alternative manner, as follows:**
 - **Without unnecessary delay in the following order of priority, starting with (A) and only proceeding to next consecutive paragraph if technically unable to fulfill request in manner identified in a paragraph.**
 - A. Using **technology certified to standard(s) adopted** in Part 170 (ONC certification rules) specified by requestor.
 - B. Using **content and transport standards specified by requestor and published by the Federal Government or an ANSI accredited standards development organization (SDO)**
 - C. Using a **mutually agreeable alternative machine-readable** format, including means to interpret EHI [Note: PDF unlikely to qualify as machine readable]
 - **Any fees charged by the Actor must satisfy the Fees Exception**
 - **Any license of interoperability elements granted by the Actor in fulfilling request must satisfy Licensing Exception**
- **If still unable to fulfill the request, use the Infeasibility Exception, being mindful of ten business day requirement to invoke this exception**

Issues Identified by the Information Blocking Workgroup

Content and Manner Exception

- If an Actor is working through the Content and Manner exception and moves to the “alternative manner” and still does not reach agreement, does the process end?
 - No. ONC states that an Actor could then turn to the Infeasibility exception
 - **But, there is a potential timing issue.** The Infeasibility exception requires the Actor to respond within 10 business days of a request, outlining the reasons that the request is infeasible. By the time an Actor finishes working through Content and Manner it could be past the 10-day requirement. ONC has taken the position that the Infeasibility timeframe applies but that the issue could be addressed in case-by-case review, with evidence of working through Content and Manner a relevant factor.

Issues Identified by the Information Blocking Workgroup

Content and Manner Exception

- Under Content and Manner, if a request is fulfilled in the **manner requested**, the Actor need not comply with Fees and Licensing exceptions but fulfilling a request in an **alternative manner** requires compliance with these exceptions.
 - The way this exception is worded could potentially allow for scenarios in which two requests are received, and fulfilled in the same manner, but one would need to comply with the Fees and Licensing exceptions and one would not. One scenario would be play out when the 2015 Edition Cures-related Updates remain in effect and two requestors (1 and 2) make similar requests to a single Actor.
 - Requestor 1 makes a request for a standards-based API functionality using FHIR R4 for USCDI information and requestor 2 makes a request for a proprietary API to access USCDI. The Actor fulfills request 1 in the manner requested and does not need to comply with the Fees or Licensing exceptions. The Actor claims an inability to meet request 2 on technical reasons and moves to offer an alternative manner which is API access using FHIR R4, and the offer is accepted by the requestor. When the Actor completes request 2 it must meet the Fees and Licensing exceptions even though it is supplying the same functionality as in request 1.
 - **Issue for ONC: Is this analysis correct and should this disparity be addressed or eliminated?**

Content and Manner: ONC FAQ

Q: How is an actor expected to fulfill a request for the USCDI under the Content and Manner Exception if they do not yet have certified health IT in place that supports the Cures Act Final Rule updates necessary to include the USCDI in certified technology?

- The “Content and Manner” exception does not require the use of any specific standard or functionality. Instead, the “Content and Manner” exception, [45 CFR 171.301](#), outlines a process by which an actor may prioritize the use of standards in fulfilling a request for EHI in a manner that supports and prioritizes the interoperability of the data. This means that, for the purposes of information blocking, before October 6, 2022, an actor may fulfill a request with the EHI identified by the data elements represented in the USCDI standard, first in the manner requested and, if not, in an alternate manner agreed upon with the requestor, following the order of priority specified in the exception

Fees Exception (1)

- Charging a fee for fulfilling a request for EHI is not prohibited by the information blocking Rule
- An Actor may charge a fee, which can include a **“reasonable profit margin,”** if any fees are:
 - ✓ charged on the basis of *objective and verifiable criteria uniformly applied* to all similarly situated persons/requests;
 - ✓ *reasonably related to the costs* of providing access, exchange, or use;
 - ✓ *reasonably allocated among all* similarly situated persons or entities that use the product/service [intended to allow approaches like sliding fee scales per comments on the Proposed Rule]; and
 - ✓ based on costs not otherwise recovered for the same instance of service to a provider and third party

Fees Exception (2)

Fees charged by Actor **must not be based:**

- ✓ in any part on whether requestor is a *competitor*, potential competitor, or will be using EHI to facilitate competition with the Actor;
- ✓ on *sales, profit, revenue*, or other value the requestor derives or may derive, *that exceed the Actor's reasonable costs*
- ✓ on *costs that led to creation of intellectual property (IP)*, if the Actor charged a royalty for *that IP* per the Licensing exception and the royalty was included in development costs for IP creation
- ✓ on costs the Actor incurred due to the health IT being *designed or implemented in a non-standard way*, unless the requestor agreed to fees associated with non-standard approach
- ✓ on certain costs associated with *intangible assets* other than actual development or acquisition costs
- ✓ on *opportunity costs* unrelated to access, exchange, or use of EHI; or
- ✓ on *anti-competitive or other impermissible criteria*
- ✓ In addition, costs excluded from the exception are: *some* data export, electronic access by individual to EHI, fees prohibited by [45 CFR 164.524\(c\)\(4\)](#) [HIPAA Privacy Rule—Access of individuals to protected health information]

Fees Exception (3)

- Actors should use detailed exception criteria for cost and pricing analyses
- Health IT developers also subject to the Conditions of Certification on fees must comply with all requirements of such conditions for all practices and at all relevant times
- **The Content and Manner exception replaces the need for this exception and its detailed requirements**
- **This exception must also be used if licensing requires fees other than royalties permissible under the Licensing exception**

Licensing Exception (1)

- An Actor that controls technologies or other interoperability elements necessary to enable access to EHI will not be information blocking if it licenses such elements under required conditions (uses the concepts of “reasonable and necessary” in specific ways but not the formal RAND model, as proposed)
 - **Negotiating** license conditions: begin negotiations within **10 business days from receipt** of a request and negotiate (in good faith) a license within **30 business days from receipt**
 - **Licensing** conditions: includes scope of rights; reasonable, non-discriminatory royalty and terms (e.g., an Actor may not charge a royalty for intellectual property (IP) if the actor recovered any development costs that led to the creation of the IP using the Fees Exception); prohibited collateral terms; permitted non-disclosure agreement terms
 - **Additional** conditions relating to provision of interoperability elements to prohibit impeding a licensee’s efforts to use licensed elements
- An Actor would **not need to license all their IP or interoperability elements per this exception to a firm that requested a license solely for developing its own technologies** and not to meet current needs for exchange, access or use of EHI to which it had a “claim” for specific patients or individual access

Licensing Exception (2)

- Much health IT software is sold via a new or existing license
- ONC expects actors to take *immediate steps to come into compliance* with this information blocking provision by amending contracts or agreements to eliminate or void any clauses that contravene this provision
- The Proposed Rule cites licensing practices that could be information blocking
- **The Content and Manner exception can enable avoiding of this exception**
- **The Fees exception must also be used if licensing requires fees other than *royalties* permissible under the Licensing exception**

Q&A: Fees and Licensing Exceptions

Is cost considered in assessing information blocking and will the cost of integration be considered in the information blocking definition?

Yes, costs, including integration costs under an actor's control, can be a factor that implicates information blocking and addressed as part of the Fees and Licensing exceptions.

Issues Identified by the Information Blocking Workgroup

Fees and Licensing

- This finalized approach is a **major departure from current practice** and could be a burden, especially for developers and HIEs
- There remains **uncertainty on the accounting granularity** needed, with more granular equaling greater burden
- There is continued **uncertainty re: needed documentation and terms** (e.g., “reasonable” costs, profits and royalties); “Reasonableness” will depend on facts and circumstances
- If an Actor must revisit all agreements and pricing, this will be very complex and time consuming – there will be an **initial period and additional ongoing review** for new *and* existing contracts and prices
- More generally, Actors will need to **establish and document processes** to ensure timely handling

Issues Identified by the Information Blocking Workgroup

Fees and Licensing

- Actors may need detailed information on customers and their competitors to ground cost/price documentation in factors like “similarly situated”
- It will be challenging to be consistent across “similarly situated” clients given variable circumstances, especially for development and implementation costs
- How often will pricing need to be revised as costs are recovered? How long should cost recovery take, especially as customers leave and arrive and products/services are updated?
- Cost allocation across customers will very challenging and need to account for allocation and reflect in prices could radically alter business practices. Should costs only be allocated over actual customers or over the potential, applicable customer base?

Issues Identified by the Information Blocking Workgroup

Fees and Licensing

- ONC outlines that the 10-day/30-day timelines to meet the Licensing exception are triggered by receipt of a request for license or use of EHI
 - It could be challenging to enter negotiation for licensing within 10-days
 - What needs to occur within the 30-day timeline? Do negotiations need to be completed within the 30-day timeframe?
 - A 30-day timeline from the point of request to complete negotiations does not seem realistic for many scenarios

Infeasibility Exception (1)

- An Actor may decline to provide access, exchange, or use of EHI in a manner that is *infeasible*. Conditions for infeasibility:
 1. The Actor cannot fulfill the request for access, exchange, or use of EHI **due to events beyond the actor's control**, namely 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. The Actor **cannot unambiguously segment** requested EHI from other EHI; or
 3. Infeasible under the circumstances as demonstrated by **contemporaneous documentation**, consistent and non-discriminatory consideration of several factors including the Content and Manner Exception and 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

Infeasibility Exception (2)

- The Actor must *respond* to infeasible requests within **ten business days** of receipt of request
- **Two factors that may not be considered** in the determination of infeasibility: (1) whether the manner requested would have **facilitated competition** with the actor; and (2) whether the manner requested **prevented the actor from charging a fee** or resulted in a reduced fee
- ONC expects Actors to attempt to use the Content and Manner exception first where it is applicable and has established a high bar for the Infeasibility Exception

Issues Identified by the Information Blocking Workgroup

Infeasibility Exception

- Can the COVID-19 emergency be used as a basis for this exception, both during the current emergency, and after, if needed organizational preparation was delayed?
 - Covid-19 has been declared a public health emergency
 - An Actor must still respond to a request within 10 business days with the reason(s) why the fulfilling the request is infeasible
- This timing may be affected by an initial, but failed effort to use the Content and Manner exception, which may make the Infeasibility Exception unavailable. In this case, ONC takes the position that a case-by-case analysis of an information blocking allegation would consider the effort to use the Content and Manner exception



Discussion



Coming Up In The Next Session

Session 5: Enforcement Issues

- In this session, we will examine the role of the HHS Office of Inspector General (OIG) for allegations of information blocking, including how they will receive complaints and determine which to investigate
- We will also review Civil Money Penalties (CMP), and the impact if they apply – or don't – to your organization
- We will provide a high-level overview of how OIG investigates and what to expect will help your organization to prepare
- Finally, we will cover the enforcement agencies for providers and the enforcement role of ONC for developers

Interoperability Matters

<https://sequoiaproject.org/interoperability-matters/>

Appendix: Regulatory Language

§ 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 electronic health information not be considered information blocking? (1)

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 electronic health information will not be considered information blocking when the practice meets all of the following conditions.

(a) *Content condition—electronic health information.* An actor must respond to a request to access, exchange, or use electronic health information with—

(1) *USCDI.* For up to May 2, 2022, at a minimum, the electronic health information identified by the **data elements** represented in the [USCDI](#) standard adopted in § 170.213.

(2) *All electronic health information.* On and after May 2, 2022, electronic health information as defined in [§ 171.102](#).

(b) *Manner condition—(1) Manner requested.*

(i) An actor must fulfill a request described in paragraph (a) of this section 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 described in paragraph (a) of this section in any manner requested:**

(A) Any fees charged by the actor in relation to fulfilling the response are **not required to satisfy the exception in § 171.302 [Fees exception]**; and

(B) Any license of interoperability elements granted by the actor in relation to fulfilling the request is **not required to satisfy the exception in § 171.303 [Licensing exception]**.

§ 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 electronic health information not be considered information blocking? (2)

(2) Alternative manner. If an actor does not fulfill a request described in paragraph (a) of this section in any manner requested because it is **technically unable to fulfill** the request **or 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) Using **technology certified** to standard(s) adopted in [part 170](#) that is specified by the requestor.

(B) Using **content and transport standards** specified by the requestor and published by:

(1) The Federal Government; or

(2) A standards developing organization accredited by the [American National Standards Institute](#).

(C) Using an **alternative machine-readable format**, including the **means to interpret the electronic health information, agreed upon** with the requestor.

(ii) **Any fees charged** by the actor in relation to fulfilling the request are **required to satisfy the exception** in § 171.302 [**Fees exception**].

(iii) **Any license of interoperability elements** granted by the actor in relation to fulfilling the request is **required to satisfy** the exception in § 171.303 [**Licensing exception**].

§ 171.302 Fees exception—when will an actor’s practice of charging fees for accessing, exchanging, or using electronic health information not be considered information blocking? (1)

An actor’s practice of charging fees, including fees that result in a reasonable profit margin, for accessing, exchanging, or using electronic health information 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 electronic health information 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.

§ 171.302 Fees exception—when will an actor’s practice of charging fees for accessing, exchanging, or using electronic health information not be considered information blocking? (2)

(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 electronic health information 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 electronic health information;
- (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 the electronic health information;
- (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 electronic health information; or
- (vi) Any **costs that led to the creation of intellectual property**, if the **actor charged a royalty** for that intellectual property pursuant to § 171.303 [**Licensing Exception**] and that royalty included the development costs for the creation of the intellectual property.

§ 171.302 Fees exception—when will an actor’s practice of charging fees for accessing, exchanging, or using electronic health information not be considered information blocking? (3)

(b) **Excluded fees condition.** This exception does not apply to—

(1) A fee prohibited by [45 CFR 164.524\(c\)\(4\)](#) [**HIPAA Privacy Rule—Access of individuals to protected health information**];

(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;

(3) A fee to perform an **export of electronic health information via the capability of health IT certified** to [§ 170.315\(b\)\(10\)](#) of this subchapter for the purposes of switching health IT or to provide patients their electronic health information; 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 Conditions of Certification** in § 170.402(a)(4), § 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.**

(d) **Definition of Electronic access.**

The following definition applies to this section: *Electronic access* means an internet-based method that makes electronic health information available at the time the electronic health information is requested and where no manual effort is required to fulfill the request.

§ 171.303 Licensing exception—when will an actor’s practice to license interoperability elements in order for electronic health information to be accessed, exchanged, or used not be considered information blocking? (1)

An actor’s **practice to license interoperability elements** for electronic health information 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 electronic health information, 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 electronic health information **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 electronic health information; and

(ii) **Achieve the intended access, exchange, or use** of electronic health information via the interoperability element(s).

§ 171.303 Licensing exception—when will an actor’s practice to license interoperability elements in order for electronic health information to be accessed, exchanged, or used not be considered information blocking? (2)

(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 (c)(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 electronic health information.
- (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 § 171.302 [**Fees Exception**] that led to the creation of the intellectual property.

§ 171.303 Licensing exception—when will an actor’s practice to license interoperability elements in order for electronic health information to be accessed, exchanged, or used not be considered information blocking? (3)

(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 electronic health information 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 electronic health information obtained via the interoperability elements.**

(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) [Permissible royalties] of this section, unless the practice meets the requirements of the exception in § 171.302 [Fees Exception].**

§ 171.303 Licensing exception—when will an actor’s practice to license interoperability elements in order for electronic health information to be accessed, exchanged, or used not be considered information blocking? (4)

(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 electronic health information for any permissible purpose.
- (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.

§ 171.204 Infeasibility exception—when will an actor’s practice of not fulfilling a request to access, exchange, or use electronic health information due to the infeasibility of the request not be considered information blocking? (1)

An actor’s practice of not fulfilling a request to access, exchange, or use electronic health information 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 meets the requirements in paragraph (b)** of this section.

(a) *Conditions*—(1) *Uncontrollable events*. The actor cannot fulfill the request for access, exchange, or use of electronic health information 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) *Segmentation*. The actor cannot fulfill the request for access, exchange, or use of electronic health information because the actor **cannot unambiguously segment** the requested electronic health information from electronic health information that:

- (i) Cannot be made available due to an **individual’s preference or because the electronic health information cannot be made available by law**; or
- (ii) May be withheld in accordance with § 171.201. [**Preventing Harm exception**]

§ 171.204 Infeasibility exception—when will an actor’s practice of not fulfilling a request to access, exchange, or use electronic health information due to the infeasibility of the request not be considered information blocking? (2)

(3) *Infeasible under the circumstances.* (i) The actor demonstrates, prior to responding to the request pursuant to paragraph (b) of this section, 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 electronic health information and the purposes for which it may be needed**;
 - (B) The **cost to the actor of complying** with the request **in the manner requested**;
 - (C) The **financial and technical resources available to the actor**;
 - (D) Whether the actor’s practice is **non-discriminatory** and the **actor provides the same access, exchange, or use of electronic health information to its companies or to its customers, suppliers, partners, and other persons with whom it has a business relationship**;
 - (E) **Whether the actor owns or has control over a predominant technology, platform, health information exchange,**
or health information network through which electronic health information is accessed or exchanged; and
 - (F) **Why the actor was unable to provide access, exchange, or use of electronic health information consistent with the exception in § 171.301. [Content and Manner exception – appears the latter exception should be attempted before resorting to the Infeasibility exception, which raises uncertainty about when to start the count for the ten business days to respond under the Infeasibility exception.]**
- (ii) In determining whether the circumstances were infeasible under paragraph (a)(3)(i) of this section, it **shall not be considered whether the manner requested** would have:
- (A) **Facilitated competition** with the actor.
 - (B) **Prevented the actor from charging a fee or resulted in a reduced fee.**

§ 171.204 Infeasibility exception—when will an actor’s practice of not fulfilling a request to access, exchange, or use electronic health information due to the infeasibility of the request not be considered information blocking? (3)

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