Information Blocking Compliance Bootcamp

Session 3: What are Information Blocking Exceptions and how should I use them?

February 17, 2021

Meet The Sequoia Project Team

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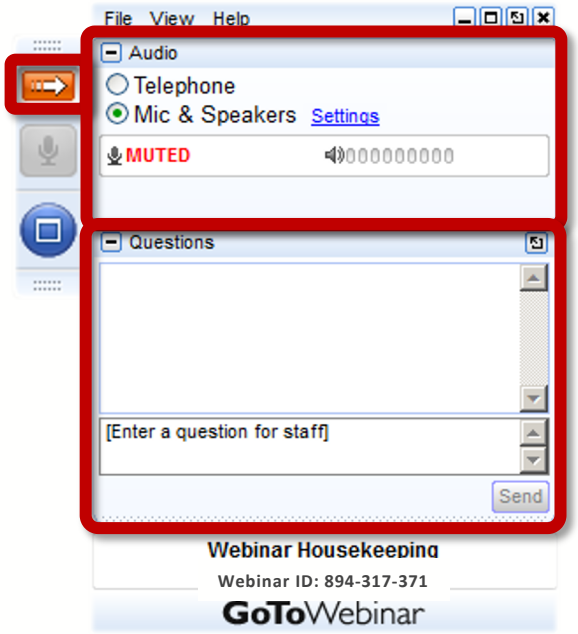
How To Participate Today



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

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.

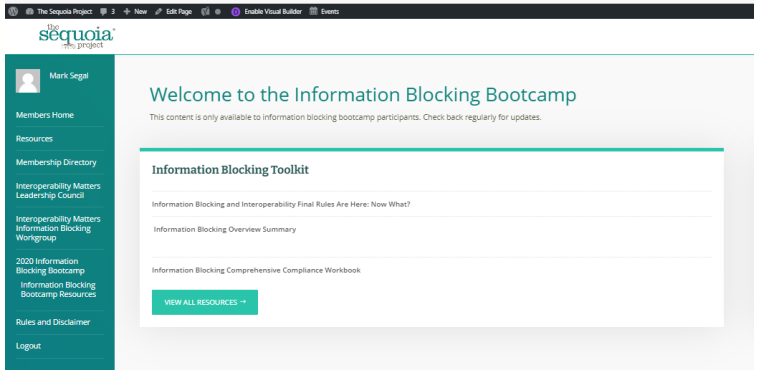
Information Blocking Compliance Boot Camp Sessions

✓ Information Blocking Overview	January 20, 2021
✓ Violating the Information Blocking Rule	February 3, 2021
3. 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 Boot Camp 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 Boot Camp sessions
- All participants that attend each Boot Camp 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
3. February 24, 2021
4. March 10, 2021
5. March 24, 2021
6. April 7, 2021
7. April 21, 2021

Quick Refresher-Practices

- Practices can be an **act or an omission** by an actor
- ONC identified many specific examples of practices in the Proposed and Final Rule but these are illustrative only and **NOT** exhaustive
- Practices can be anything that interferes with access, exchange or use of EHI
- A practice is not an automatic information blocking violation, an Actor must have the required knowledge or intent to interfere with access, exchange or use of EHI
- The practice must not fall within an exception or otherwise be required by law

Session 3: Exceptions – Part 1

Session Goals

- This initial session on Exceptions will be an overview of the way ONC organizes exceptions in the Final Rule, and what we can infer from changes made in the Final Rule
- We will review the role of the elements to each exception and what it means to meet an exception and document compliance
- We will also begin detailed review of the Preventing Harm, Privacy, Security, and Health IT Performance Exceptions

Exceptions: An Overview

What is the Legal Basis for the Exceptions?

- "Exception" is a term included in definition of Information Blocking in the ONC Final Rule to implement a concept in the Cures definition of Information Blocking
- Congress directed ONC to identify activities that were "reasonable and necessary" to achieve a greater public purpose despite the likelihood that the practice would be information blocking
- Cures (Section 4004)

  A practice by a health care provider, health IT developer, health information exchange, or health information network that, except as required by law ***or specified by the Secretary as a reasonable and necessary activity****, is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information*
- ONC Final Rule (§ 171.103 Information blocking)

  (a) Information blocking means a practice that–

  (1) Except as required by law ***or covered by an exception*** *set forth in subpart B or subpart C of this part, is likely to interfere with access, exchange, or use of electronic health information*

Finalized Exceptions and their Role

- Responding to comments, in the Final Rule ONC revised the proposed exceptions, added an eighth exception, provided guidance and examples, and divided the exceptions into two categories:
  1. Not fulfilling requests to access, exchange, or use EHI
  2. Procedures for fulfilling requests to access, exchange, or use EHI
- ONC changed the titles of each exception into a question format to reinforce that each exception includes practices likely to interfere with the access, exchange or use of EHI
- Many **documentation requirements** are embedded in exception conditions; in all cases, **documentation of how exception conditions are met will be essential**
- **Failing to meet conditions of 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 (e.g., level of impact, intent, knowledge)**

Exceptions: ONC FAQ

Q: If an actor does not fulfill a request for access, exchange, and use of EHI in "any manner requested" that they have the technical capability to support, is the actor automatically an information blocker unless they satisfy at least one of the information blocking exceptions?

- Not necessarily. The eight information blocking exceptions defined in 45 CFR part 171 are voluntary and offer actors certainty that any practice meeting the conditions of one or more exceptions will not be considered information blocking. However, an actor's practice that does not meet the conditions of an exception will not automatically constitute information blocking. Instead such practices will be evaluated on a case-by-case basis to determine whether information blocking has occurred.
- Whether information blocking occurred in a particular case would be based 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.

Exceptions: ONC FAQ (2)

- Please note, the knowledge standard varies based on the type of actor.
  - For health care providers, the standard is that the actor "knows that such practice is unreasonable and is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information."
  - For health IT developers of certified health IT and health information networks (HINs) or health information exchanges (HIEs) the standard is that the actor "knows, or should know, that such practice is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information." In addition, we recommend review of the examples included in the Final Rule of what is and is not considered interference at 85 FR 25811.

What Eight Exceptions are Identified by ONC?

Not Fulfilling Requests to Access, Exchange, or Use EHI

1. Preventing Harm
2. Privacy
3. Security
4. Infeasibility
5. Health IT Performance

Procedures for Fulfilling Requests to Access, Exchange, or Use EHI

6. Content and Manner
7. Fees
8. Licensing

How Do You Use Exceptions?

- Exceptions are an affirmative defense to a claim that a practice is information blocking
- Burden is on an actor to demonstrate that its practice meets an exception
  - You cannot simply assert an exception and require the OIG to prove that you don't meet it
- Actor must prove it meets **every element** of the exception(s) that it is asserting

Handling Exceptions within Your Organization

- Using exceptions effectively will require a **plan**, **careful documentation**, **coordination**, and **accountability**
- Each exception will involve **team members from across your organization;** examples are in the *Compliance Planning Workbook*
- You will want to **sequence some exceptions strategically** (e.g., Content and Manner before Fees, Licensing, or Infeasibility)
- Some exceptions have a **"time clock"** in which they must be claimed or elements applied (e.g., response to an inquiry)
- Exceptions will be relevant for responses to data requests and with enforcement agencies as needed

Exceptions: Part 1

Preventing Harm Exception (1)

- An actor may engage in practices that are **reasonable and necessary** to **prevent harm** to a patient or another person
- The actor must have a **reasonable belief** the practice will substantially reduce the likelihood of harm to a patient or another person
- The **type of harm** being prevented must be harm that a HIPAA covered entity could use to deny access to an individual's PHI under the Privacy Rule's Right of Access (45 CFR 162.524 (a)(3))
  - Access requested is "reasonably likely to **endanger the life or physical safety**" of the individual or another person (45 CFR 162.524 (a)(3)(1)) **IF** the practice affects the individual's access, exchange or use of their own EHI **or the request is not otherwise covered in the first three conditions (e.g., provider request)**
  - Access requested is "**reasonably likely to cause substantial harm** to another person" if the PHI references another person
  - Access is "reasonably likely to cause substantial harm to the individual or another person" if requested by the individual's legal representative

Preventing Harm Exception (2)

- Except for request from the individual or "other" category, **risk of harm** must:
  - be determined on an **individualized basis** in the exercise of **professional judgment** by a **licensed health care professional** who has a current or prior clinician-patient relationship with the patient whose EHI is affected by the determination; **OR**
  - arise from data known or reasonably suspected to be **misidentified or mismatched**, **corrupt** due to technical failure, or **erroneous** for another reason
- The practice must be **no broader than necessary** to substantially reduce the risk of harm that the practice is implemented to reduce
- Must based on either:
  - an **organizational policy** that is in writing, based on relevant clinical, technical and other appropriate expertise and implemented in a consistent and non-discriminatory manner; **OR**
  - **individualized determination** based on facts/circumstances known or reasonably believed at the time and relevant expertise

Privacy Exception (1)

- An actor may refuse to fulfill a request to access, exchange or use EHI **to protect an individual's privacy**
- This exception is unique because it contains **four sub-exceptions**, each with its own requirements:
  1. Preconditions prescribed by laws are not satisfied (e.g., required consent);
  2. Health IT developer of certified health IT is not covered by HIPAA (i.e., developer that is not a BA for a patient facing product or service) but that implement documented and transparent privacy policies;
  3. Denial of an individual's request for their electronic protected health information in the circumstances provided in 45 CFR 164.524(a)(1) and (2) (unreviewable grounds for denying patient right of access); or
  4. Respecting an individual's request not to share information
- You must meet all the elements of **at least one** sub-exception
- Note: "Individual" is defined more broadly than in HIPAA to include others who have the legal authority to act on behalf of a patient such as spouse

Privacy Exception (2)

- Sub-exception #1 – Precondition not satisfied
  - Precondition must be **required by law or regulation**; ONC expressed concern that this sub-exception not be used as a "pretext" to refuse to fulfill a request
  - Actor's privacy-protective practices must be based on **objective criteria** that are applied uniformly for all substantially similar privacy risks
  - Practices must be **tailored** to the specific privacy risk and the legal pre-condition (e.g., identity verification)

Privacy Exception (3)

- Sub-exception #2– Health IT developer not covered by HIPAA
  - Does **not** apply if health IT developer is a business associate of a Covered Entity
  - Would apply to health IT developer of certified health IT involved in only direct-to-consumer products or services
  - Practice **must** be described in detail in actor's privacy policy (e.g., blanket requirement of customer consent not valid absent rationale for why prior consent is necessary)
  - Practice **must** be disclosed in advance in plain language
  - Practice must be tailored

Privacy Exception (4)

- Sub-exception #3 – Patient right of access
  - Limited to the "unreviewable" grounds for denying access to PHI under the HIPAA Privacy Rule (45 CFR 162.524 (A)(1) and (2))
    - Requests by inmates of correctional institution
    - Requests by individual participants in focused study while study in process
    - Records subject to the Privacy Act (5 USC 552a) if disclosure is prohibited
    - Information from non-healthcare provider under a promise of confidentiality
    - Psychotherapy notes
    - Information compiled in reasonable anticipation of, or in use in, civil, criminal or administrative action or procedure
  - Proposed Rule included "reviewable" grounds under HIPAA but those are now covered by Preventing Harm exception

Privacy Exception (5)

- Sub-exception #4 – Respecting individual's request to not share information
  - Allows actors to respect an individual's privacy choices without fear of information blocking
  - Request must come from the individual, be documented by the actor and implemented in a consistent, non-discriminatory manner
  - No interference or pressure on the individual to make the request

Privacy Exception (6)

- Actors need not provide access, exchange, or use of EHI in a manner **not permitted** under the HIPAA Privacy Rule
- Actors operating in **multiple states** can rely on an organizational policy that adopts the most stringent state law for the entire organization
- ONC emphasizes that information blocking provision **may require actors to provide access, exchange, or use of EHI in situations where HIPAA would not require access** of similar information (e.g., HIPAA Privacy Rule **permits**, **but does not require**, covered entities to disclose ePHI in most situations)

Security Exception (1)

- An actor may engage in a practice that is likely to interfere with the access, exchange or use of EHI to **promote security of EHI** provided the practice is:
  - **Directly related to safeguarding** confidentiality, integrity, and availability of EHI
  - **Tailored** to specific security risks being addressed
  - Implemented in a **consistent and non-discriminatory manner**
  - **If implementing an organizational security policy it must:**
    - Be in writing
    - Prepared for/be directly responsive to security risks identified by actor
    - Align with consensus-based standards/best practices
    - Provide objective timeframes/other parameters for identifying, responding to and addresses security incidents
  - If not implementing an organizational security policy, the practice must be based on specific facts and circumstances that the practice is necessary to mitigate risks and there is no reasonable alternative

Security Exception (2)

- ONC uses a **fact-based approach** to allow each actor to implement policies, procedures, and technologies **appropriate for its size, structure,** and **risks** to individuals' EHI
- The **intent is to prohibit practices** that "purport to promote the security of EHI but that are **unreasonably broad and onerous** on those seeking access to EHI, **not applied consistently** across or within an organization, or otherwise may **unreasonably interfere** with access, exchange, or use of EHI"
- Would apply to **security practices exceeding minimum HIPAA Security conditions**

Health IT Performance Exception (1)

- An actor's practices to maintain or improve health IT performance, even if those practices are likely to interfere with access, exchange or use of EHI are permitted under strict conditions
- For maintenance or improvements to health IT that make the health IT temporarily unavailable or temporarily degraded if:
  - The interruption lasts no longer than necessary, ONC said adopting specific timeframes was not practical
  - Implemented in a fair and consistent manner
  - "Planned" interruptions must be consistent with existing SLAs
  - "Unplanned" interruptions must be consistent with existing SLAs **or** agreed to
- Obligations differ if the Actor is a health IT developer or a provider
- ONC notes that a period of health IT unavailability or performance degradation could be within the parameters of the SLA but "longer than necessary" and potentially information blocking or conversely outside the parameters of the SLA without being "longer than necessary" and, therefore, without necessarily being information blocking **[Likely becomes a case-by-case issue]**

Health IT Performance Exception (2)

- An actor **may take action against a third-party application** (including but not limited to patient-facing apps) that is **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 SLAs**, where applicable
- **Harm, Security, or Infeasibility (e.g., disaster)-related practices** are addressed by or must also be consistent with those exceptions
- **Document the SLA or case-by-case factors** given exception criteria

Discussion

Coming Up In The Next Session

Session 4: Exceptions—Part 2

- We will make a detailed review of the remaining exceptions: including Infeasibility, Content and Manner, Fees, and Licensing
- We will also address interactions and sequencing of the exceptions

Interoperability Matters

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

Appendix: Regulatory Language

§ 171.201 Preventing Harm Exception — When will an actor's practice that is likely to interfere with the access, exchange, or use of electronic health information in order to prevent harm not be considered information blocking? (1)

An actor's practice that is likely to interfere with the access, exchange, or use of electronic health information in order to prevent harm will not be considered information blocking when the practice meets the conditions in paragraphs (a) and (b) of this section, **satisfies at least one condition (subparagraph) from each of paragraphs (c), (d) and (f) of this section, and also meets the condition in paragraph (e) of this section when 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 a patient or another natural person that would otherwise arise from the access, exchange, or use of electronic health information affected by the practice. For purposes of this section, "patient" means a natural person who is the subject of the electronic health information 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 risk.* The risk of harm must:

(1) Be **determined on an individualized basis in the exercise of professional judgment by a licensed health care professional who has a current or prior clinician-patient relationship** with the patient whose EHI is affected by the determination; ***or***

(2) **Arise from data that is known or reasonably suspected** to be misidentified or mismatched, corrupt due to technical failure, or erroneous for another reason.

§ 171.201 Preventing Harm Exception — When will an actor's practice that is likely to interfere with the access, exchange, or use of electronic health information in order to prevent harm not be considered information blocking? (2)

(d) *Type of harm.* The **type of harm must be one that could serve as grounds for a covered entity (as defined in § 160.103 of this title) to deny access** (as the term "access" is used in part 164 of this title) to an individual's protected health information under:

(1) Section 164.524(a)(3)(iii) of this title where the practice is likely to, or in fact does, interfere with **access, exchange, or use** (as these terms are defined in § 171.102) of the patient's EHI by their **legal representative** (including but not limited to personal representatives recognized pursuant to 45 CFR 164.502) and the practice is implemented pursuant to an individualized determination of risk of harm consistent with (c)(1) of this section;

(2) Section 164.524(a)(3)(ii) of this title where 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 these terms are defined in § 171.102) 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) Section 164.524(a)(3)(i) of this title where the practice is likely to, or in fact does, interfere with the **patient's access, exchange, or use** (as these terms are defined in § 171.102) of their own EHI, **regardless of whether the risk of harm that the practice is implemented to substantially reduce is consistent with paragraph (c)(1) or (c)(2)** of this section; **or**

(4) Section 164.524(a)(3)(i) of this title where the practice is likely to, or in fact does, interfere with a legally permissible access, exchange, or use (as these terms are defined in § 171.102) of electronic health information not described in paragraph (d)(1), (2), or (3) of this section, and **regardless of whether the risk of harm the practice is implemented to substantially reduce is consistent with paragraph (c)(1) or (2)** of this section.

§ 171.201 Preventing Harm Exception — When will an actor's practice that is likely to interfere with the access, exchange, or use of electronic health information in order to prevent harm not be considered information blocking? (3)

(e) *Patient right to request review of individualized determination of risk of harm.* Where the risk of harm is **consistent with paragraph (c)(1)** of this section, the actor must implement the practice in a manner consistent with any rights the individual patient whose electronic health information is affected **may have under § 164.524(a)(4) of this title, or any Federal, State, or tribal law, to have the determination reviewed and potentially reversed**.

§ 171.201 Preventing Harm Exception — When will an actor's practice that is likely to interfere with the access, exchange, or use of electronic health information in order to prevent harm not be considered information blocking? (4)

(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 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 that are applicable to the practice and its use**.

(2) A **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 that are applicable to the practice and its use in particular circumstances.

§ 171.202 Privacy Exception — When will an actor's practice of not fulfilling a request to access, exchange, or use electronic health information in order to protect an individual's privacy not be considered information blocking? (1)

An actor's practice of not fulfilling a request to access, exchange, or use electronic health information in order to protect an individual's privacy will not be considered information blocking when the **practice meets all of the requirements of at least one of the sub-exceptions** in parag**raphs (b) through (e)** of this section.

(a) ***Definitions*** *in this section.*

(1) The term *HIPAA Privacy Rule* as used in this section means 45 CFR parts 160 and 164.

(2) The term *individual* as used in this section means one or more of the following—

(i) An individual as defined by 45 CFR 160.103.

(ii) Any other natural person who is the subject of the electronic health information 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 health care as a personal representative, in accordance with 45 CFR 164.502(g).

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

(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.

§ 171.202 Privacy Exception — When will an actor's practice of not fulfilling a request to access, exchange, or use electronic health information in order to protect an individual's privacy not be considered information blocking? (2)

(b) ***Sub-Exception – Precondition 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 electronic health information 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**.

§ 171.202 Privacy Exception — When will an actor's practice of not fulfilling a request to access, exchange, or use electronic health information in order to protect an individual's privacy not be considered information blocking? (2)

(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 subsections (b)(1)(i) and (b)(2) above **when the actor's operations are subject to multiple laws which have inconsistent preconditions**, they shall be deemed to **satisfy the requirements of the subsections if the actor has adopted uniform privacy policies and procedures to address the more restrictive preconditions**.

§ 171.202 Privacy Exception — When will an actor's practice of not fulfilling a request to access, exchange, or use electronic health information in order to protect an individual's privacy not be considered information blocking? (3)

(c) ***Sub-exception—health IT developer of certified health IT not covered by HIPAA.*** If the **actor is a health IT developer of certified health IT 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**.

Note: ONC states that "the vast majority of health IT developers of certified health IT operate as business associates to covered entities under HIPAA. As business associates, they are regulated by the HIPAA Privacy Rule" and would not need this sub-exception.

(d) **Sub-exception—denial of an individual's request for their electronic health information** consistent with 45 CFR 164.524(a)(1) and (2). If an individual requests electronic health information under the **right of access provision** under 45 CFR 164.524(a)(1) from an actor that must comply with 45 CFR 164.524(a)(1), the actor's practice must be consistent with 45 CFR 164.524(a)(2).

§ 171.202 Privacy Exception — When will an actor's practice of not fulfilling a request to access, exchange, or use electronic health information in order to protect an individual's privacy not be considered information blocking? (4)

(e) ***Sub-exception—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 electronic health information if the following requirements are met**—

(1) The **individual requests that the actor not provide such access, exchange, or use** of electronic health information **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 electronic health information 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 electronic health information except that such termination is**:

(A) **Not effective to the extent prohibited by applicable Federal or State law**; and

(B) Only **applicable to electronic health information created or received after the actor has so informed the individual of the termination**.

§ 171.203 Security Exception—when will an actor's practice that is likely to interfere with the access, exchange, or use of electronic health information in order to protect the security of electronic health information not be considered information blocking?

An actor's practice that is likely to interfere with the access, exchange, or use of electronic health information in order to protect the security of electronic health information will **not be considered information blocking when the practice meets the conditions in paragraphs (a), (b), and (c) of this section**, and in addition **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 electronic health information**.

(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**.

(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**.

(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 electronic health information**; **and**

(2) 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 electronic health information. [Note: Revised in 11/4/2020 ONC Interim Final Rule with Comment]

§ 171.205 Health IT Performance Exception—when will 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 electronic health information not be considered information blocking? (1)

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 electronic health information **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, in order 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 of certified health IT, health information exchange, or health information network**:

(i) ***Planned.*** **Consistent with existing service level agreements** between the individual or entity to whom the health IT developer of certified health IT, health information exchange, or health information network 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 of certified health IT, health information exchange, or health information network **supplied the health IT**.

§ 171.205 Health IT Performance Exception—when will 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 electronic health information not be considered information blocking? (2)

(b) *Assured level of performance.* An actor may take **action against a third-party application that is 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. **[Harm 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 electronic health information, the actor does not need to satisfy the requirements of this section, but must comply with all requirements of § 171.203 at all relevant times to qualify for an exception. **[Security Exception]**