Information Blocking Exceptions

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

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

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

The full text of the information blocking regulations can be found in 45 CFR part 171. Please note that other federal, state, and local laws may also apply.

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

- Preventing Harm Exception
- Privacy Exception
- Security Exception
- Infeasibility Exception
- Health IT Performance Exception

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

- Manner Exception
- Fees Exception
- Licensing Exception

Exceptions that involve practices related to actors' participation in the Trusted Exchange Framework and Common Agreement (TEFCA)

- TEFCA Manner Exception

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

Preventing Harm Exception

It will not be information blocking for an actor to engage in practices that are reasonable and necessary to prevent harm to a patient or another person, provided certain conditions are met.

Objective of the Exception:
This exception recognizes that the public interest in protecting patients and other persons against unreasonable risks of harm can justify practices that are likely to interfere with access, exchange, or use of EHI.

Key Conditions of the Exception

- The actor must hold a reasonable belief that the practice will substantially reduce a risk of harm;

- The actor's practice must be no broader than necessary;

- The actor's practice must satisfy at least one condition from each of the following categories: type of risk, type of harm, and implementation basis; and

- The practice must satisfy the condition concerning a patient right to request review of an individualized determination of risk of harm.

Privacy Exception

It will not be information blocking if an actor does not fulfill a request to access, exchange, or use EHI in order to protect an individual's privacy, provided certain conditions are met.

Objective of the Exception:
This exception recognizes that if an actor is permitted to provide access, exchange, or use of EHI under a privacy law, then the actor should provide that access, exchange, or use. However, an actor should <u>not</u> be required to use or disclose EHI in a way that is prohibited under state or federal privacy laws.

Key Conditions of the Exception
To satisfy this exception, an actor's privacy-protective practice must meet at least one of the four sub-exceptions:

1. ***Precondition not satisfied:*** If an actor is required by a state or federal law to satisfy a precondition (such as a patient consent or authorization) prior to providing access, exchange, or use of EHI, the actor may choose not to provide access, exchange, or use of such EHI if the precondition has not been satisfied under certain circumstances.

2. ***Health IT developer of certified health IT not covered by HIPAA:*** If an actor is a health IT developer of certified health IT that is not required to comply with the HIPAA Privacy Rule, the actor may choose to interfere with the access, exchange, or use of EHI for a privacy-protective purpose if certain conditions are met.

3. ***Denial of an individual's request for their EHI consistent with 45 CFR 164.524(a)(1) and (2):*** An actor that is a covered entity or business associate may deny an individual's request for access to his or her EHI in the circumstances provided under 45 CFR 164.524(a)(1) and (2) of the HIPAA Privacy Rule.

4. ***Respecting an individual's request not to share information:*** An actor may choose not to provide access, exchange, or use of an individual's EHI if doing so fulfills the wishes of the individual, provided certain conditions are met.

Security Exception

It will not be information blocking for an actor to interfere with the access, exchange, or use of EHI in order to protect the security of EHI, provided certain conditions are met.

Objective of the Exception:
This exception is intended to cover all legitimate security practices by actors, but does not prescribe a maximum level of security or dictate a one-size-fits-all approach.

Key Conditions of the Exception

- The practice must be:
    1. Directly related to safeguarding the confidentiality, integrity, and availability of EHI;
    2. Tailored to specific security risks; *and*
    3. Implemented in a consistent and non-discriminatory manner.

- The practice must either implement a qualifying organizational security policy or implement a qualifying security determination.

Infeasibility Exception

It will not be information blocking if an actor does not fulfill a request to access, exchange, or use EHI due to the infeasibility of the request, provided certain conditions are met.

Objective of the Exception:
This exception recognizes that legitimate practical challenges may limit an actor's ability to comply with requests for access, exchange, or use of EHI. An actor may not have—and may be unable to obtain— the requisite technological capabilities, legal rights, or other means necessary to enable access, exchange, or use.

Key Conditions of the Exception

- The practice must meet one of the following conditions:
  » Uncontrollable events: The actor cannot fulfill the request for access, exchange, or use of electronic health information because of 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 that in fact negatively impacts the actor's ability to fulfill the request.
  » Segmentation: The actor cannot fulfill the request for access, exchange, or use of EHI because the actor cannot unambiguously segment the requested EHI.
  » Third party seeking modification use: The request is to enable use of EHI in order to modify EHI provided that the request for such use is not from a health care provider requesting such use from an actor that is its business associate.
  » Infeasibility under the circumstances: The actor demonstrates through a contemporaneous written record or other documentation its consistent and non-discriminatory consideration of certain factors that led to its determination that complying with the request would be infeasible under the circumstances.
  » Manner exception exhausted: The actor does not fulfill a request for access, exchange, or use of EHI after offering alternative, interoperable manners. This condition only applies under certain circumstances where the actor does not currently provide the requested manner of access, exchange, or use of the requested EHI to a substantial number of individuals or entities that are similarly situated to the requestor.
- The actor must provide a written response to the requestor within 10 business days of receipt of the request with the reason(s) why the request is infeasible.

Health IT Performance Exception

It will not be information blocking for an actor to take reasonable and necessary measures to make health IT temporarily unavailable or to degrade the health IT's performance for the benefit of the overall performance of the health IT, provided certain conditions are met.

Objective of the Exception:
This exception recognizes that for health IT to perform properly and efficiently, it must be maintained, and in some instances improved, which may require that health IT be taken offline temporarily. Actors should not be deterred from taking reasonable and necessary measures to make health IT temporarily unavailable or to degrade the health IT's performance for the benefit of the overall performance of health IT.

Key Conditions of the Exception

- The practice must:
  1. Be implemented for a period of time no longer than necessary to achieve the maintenance or improvements for which the health IT was made unavailable or the health IT's performance degraded;
  2. Be implemented in a consistent and non-discriminatory manner; and
  3. Meet certain requirements if the unavailability or degradation is initiated by a health IT developer of certified health IT, HIE, or HIN.
- An actor may take action against a third-party app 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.
- If the unavailability is in response to a risk of harm or security risk, the actor must only comply with the Preventing Harm or Security Exception, as applicable.

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

Manner Exception

It will not be information blocking for an actor to limit the manner in which it fulfills a request to access, exchange, or use EHI, provided certain conditions are met.

Objective of the Exception:

This exception provides clarity and flexibility to actors concerning the required manner in which the actor may fulfill the request. This exception supports innovation and competition by allowing actors to first attempt to reach and maintain market negotiated terms for the access, exchange, and, use of EHI.

Key Condition of the Exception

- *Manner Exception:* Establishes the manner in which an actor must fulfill a request to access, exchange, or use EHI in order to satisfy this exception.

  » An actor may need to fulfill a request in an **alternative manner** when the actor is:

    – Technically unable to fulfill the request in any manner requested; *or*
    – Cannot reach agreeable terms with the requestor to fulfill the request.

  » If an actor fulfills a request in an alternative manner, such fulfillment must comply with the order of priority described in the Manner Exception and must satisfy the Fees Exception and Licensing Exception, as applicable.

Fees Exception

It will not be information blocking for an actor to charge fees, including fees that result in a reasonable profit margin, for accessing, exchanging, or using EHI, provided certain conditions are met.

Objective of the Exception:

This exception enables actors to charge fees related to the development of technologies and provision of services that enhance interoperability, while not protecting rent-seeking, opportunistic fees, and exclusionary practices that interfere with access, exchange, or use of EHI.

Key Conditions of the Exception

The practice must:

- Meet the basis for fees condition.

  » For instance, the fees an actor charges must:
    – Be based on objective and verifiable criteria that are uniformly applied for all similarly situated classes of persons or entities and requests.
    – Be reasonably related to the actor's costs of providing the type of access, exchange, or use of EHI.
    – Not be based on 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.

- Not be specifically excluded.

  » For instance, the exception does not apply to:
    – A fee based in any part on the electronic access by an individual, their personal representative, or another person or entity designated by the individual to access the individual's EHI.
    – A fee to perform an export of electronic health information via the capability of health IT certified to § 170.315(b)(10).

- Comply with Conditions of Certification in § 170.402(a)(4) (Assurances – certification to "EHI Export" criterion) or § 170.404 (API).

Licensing Exception

It will not be information blocking for an actor to license interoperability elements for EHI to be accessed, exchanged, or used, provided certain conditions are met.

Objective of the Exception:
This exception allows actors to protect the value of their innovations and charge reasonable royalties in order to earn returns on the investments they have made to develop, maintain, and update those innovations.

Key Conditions of the Exception

The practice must meet:

- The negotiating a license conditions: An actor must begin license negotiations with the requestor within 10 business days from receipt of the request and negotiate a license within 30 business days from receipt of the request.
- The licensing conditions:
  - » Scope of rights
  - » Reasonable royalty
  - » Non-discriminatory terms
  - » Collateral terms
  - » Non-disclosure agreement
- Additional conditions relating to the provision of interoperability elements.

Exceptions that involve practices related to actors' participation in the Trusted Exchange Framework and Common Agreement (TEFCA)

TEFCA Manner Exception

It will not be information blocking for an actor to fulfill certain requests for access, exchange, or use of EHI only via TEFCA, provided certain conditions are met.

Objective of the Exception:
This exception encourages secure, efficient, standards-based exchange of electronic health information under the Trusted Exchange Framework and Common Agreement (TEFCA).

Key Conditions of the Exception

The HTI-1 final rule establishes a "TEFCA Manner" Exception that applies where an actor and requestor are both part of TEFCA. Where the exception is met, an actor's practice of fulfilling certain requests for access, exchange, or use of EHI only via TEFCA will not be considered information blocking. The exception applies only where:

- The actor and requestor are both part of TEFCA;
- Access, exchange, or use of the requested EHI can be supported via TEFCA for both the actor and requestor;
- The request for access, exchange or use is not via API standards adopted under the ONC Health IT Certification Program;
- Any fees charged and any licensing of interoperability elements by the actor in relation to fulfilling the request via TEFCA satisfy, respectively, the Fees Exception (§ 171.302) and Licensing Exception (§ 171.303).