

HTI-1 INFORMATION BLOCKING FACT SHEET Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Final Rule

December 2023

# Information Blocking Updates: Definitions, and Exceptions

## **Information Blocking Definitions**

### "Offer Health IT"

The HTI-1 final rule defines what it means to "<u>offer health IT</u>" for purposes of the information blocking regulations. This definition confirms that proffering or supplying any certified health IT to be deployed by others will generally be considered an offer of health IT, while confirming that certain implementation and use activities are not considered an offer. The finalized definition also narrows the potential applicability of the "health IT developer of certified health IT" definition by explicitly excluding certain activities from what it means to "offer" health IT.

### "Health IT Developer of Certified Health IT"

The HTI-1 final rule changes the wording in the "<u>health IT developer of certified health IT</u>" definition so that it remains clear that a health care provider that self-develops certified health IT will not be considered a health IT developer of certified health IT if the provider does not "offer" any certified health IT.

#### "Information Blocking"

The HTI-1 final rule revises the definition of "information blocking" to remove language that was no longer applicable. Specifically, ONC removed language that applied before October 6, 2022, that limited the definition to the subset of <u>electronic health information</u> (EHI) represented by data elements identified in the USCDI v1).

## Information Blocking Exceptions

Exceptions are voluntary and provide assurance to actors that, when a practice meets the exception, it will not constitute information blocking. ONC revised two exceptions and created a new exception.

#### **Infeasibility Exception**

The HTI-1 final rule revises one condition and creates two new conditions for the Infeasibility Exception.

#### **The Uncontrollable Events Condition**

A revision to the "<u>uncontrollable events</u>" condition further clarifies when an actor's practice meets the "uncontrollable events" condition. Where this condition is met and the overall exception is met, it will not be considered information blocking when an actor does not fulfill a request to access, exchange, or use EHI that the actor cannot fulfill because of an uncontrollable event.

#### **The Third Party Seeking Modification Use Condition**

ONC added a new "<u>third party seeking modification use</u>" condition. Where this condition is met and the overall exception is met, an actor's practice of not fulfilling a request for use of EHI will not be considered information blocking when:

- the actor is asked to enable a third party to:
- modify EHI within the records or systems maintained by the actor; and





• the request is not from a health care provider (including a business associate acting on the health care provider's behalf) requesting such use from an actor that is its business associate.

#### **Manner Exception Exhausted**

The new "<u>manner exception exhausted</u>" condition applies where an 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.

#### **Manner Exception**

Because the October 6, 2022 date before which the "content" condition was relevant has now passed, the HTI-1 final rule revises the exception. The final rule:

- removes the "content" condition as no longer necessary
- changes the name from "<u>Content and Manner Exception</u>" to "Manner Exception," and
- finalizes redesignation of paragraphs within the "Manner Exception" consistent with removal of the "content" condition.

#### New Exception for Actors and Requestors Capable of Exchange via TEFCA

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 finalized 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)

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• learn more and find links to the actual definitions and exceptions at HealthIT.gov



Visit healthit.gov/HTI-1 for additional information.

The HTI-1 rule includes updates to definitions for the information blocking regulations, and new and revised exception coverage applicable in certain circumstances. The HTI-1 rule preamble addresses feedback from interested parties and provides additional information about regulatory defined terms and the application of information blocking exceptions.