

Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Proposed Rule

May 2023

The HTI-1 proposed rule proposes updates to definitions for the information blocking regulations, and new and revised conditions for certain exceptions. The HTI-1 proposed rule addresses feedback from interested parties seeking additional information about regulatory defined terms and the application of information blocking exceptions. For important background on the proposals made in the HTI-1 proposed rule, please first visit the [ONC Health IT Buzz Blog](#).

What Information Blocking Definitions Does the Proposed Rule Address?

“Offer Health IT”

ONC proposes to define what it means to “[offer health IT](#)” for purposes of the information blocking regulations. This definition would narrow the potential applicability of the “health IT developer of certified health IT” definition through explicit exclusions of certain activities from what it means to “offer” health IT.

“Health IT Developer of Certified Health IT”

ONC proposes to modify the definition of a “[health IT developer of certified health IT](#)” so that it remains clear that health care providers who self-develop certified health IT would continue to be excluded from this definition if they do not offer certified health IT to others.

“Information Blocking”

ONC proposes to revise the definition of “information blocking” to remove the period of time for which it was limited to the subset of [electronic health information](#) (EHI) represented by data elements identified in the USCDI v1 because that time has passed. As of October 6, 2022, the information blocking definition applies to all [EHI](#).

What Information Blocking Exceptions Does the Proposed Rule Address?

Infeasibility Exception

ONC proposes to revise one condition and create two new conditions for the [Infeasibility Exception](#).

Uncontrollable Events

A revision to the “[uncontrollable events](#)” [condition](#) would further clarify when an actor’s practice meets the “uncontrollable events” condition such that it would not be information blocking if an actor does not fulfill a request to access, exchange, or use EHI.

Third Party Seeking Modification Use

ONC proposes to add a new “[third party seeking modification use](#)” condition. This condition would apply in certain situations where:

- the actor is asked to provide the ability for a third party (or its technology, such as an app);
- to modify EHI (including but not limited to creation and deletion functionality); 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 proposed new “[manner exception exhausted](#)” condition would apply where an actor does not fulfill a request for access, exchange, or use of EHI after offering alternative, interoperable manners.
- The condition would only apply 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, ONC proposes to revise the exception to remove that condition as no longer necessary and change the name from “[Content and Manner Exception](#)” to “Manner Exception.”
- ONC proposes to add a “[TEFCA manner](#)” condition to the Manner Exception, which acknowledges that certain agreements have been reached between Qualified Health Information Networks (QHINs), participants, and sub-participants for the access, exchange, and use of EHI, and allows such actors to decline to offer requested EHI in any other manner if the actor offers to fulfill requests from QHINs, participants, and sub-participants using services consistent with applicable Framework Agreement(s). The proposed TEFCA manner condition would apply for any and all [EHI](#) for which access, exchange, or use of EHI can be supported by TEFCA means for both the actor and requestor, for any purpose permitted under the Common Agreement and applicable Framework Agreement(s).



Visit healthit.gov/proposedrule for additional information. More updates will be added over time.

Disclaimer: This fact sheet describes select proposals described in the Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) proposed rule. While every effort has been made to ensure the accuracy of this fact sheet, it is not a legal document. Please refer to the HTI-1 proposed rule for full provision details.

