



Information Blocking Requirements for Certified Health IT

Key Information about Information Blocking in HTI-1

- The Office of the National Coordinator (ONC) finalized a revised definition of “Information Blocking.”
- ONC revised definitions of “a developer of certified health IT” and an actor that “offers Health IT” to clarify what actors are within scope of information blocking requirements and therefore are subject to civil monetary penalties.
 - Eligible clinicians and hospitals are subject to disincentives, proposed in the 21st Century Cures Act: Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking published by the Centers for Medicare and Medicaid Services and ONC on November 1, 2023.
- ONC revised two exceptions to Information Blocking requirements:
 - Uncontrollable Events component of the infeasibility exception now mandates that the actor must demonstrate the information blocking activity was directly caused by an uncontrollable event.
 - Manner Exception was revised to remove “Content” from the former Content and Manner Exception. Content was deemed to be redundant terminology for EHI.
- ONC finalized two new Information Blocking exception conditions:
 - The Infeasibility exception now includes a condition allowing actors to deny the ability to modify electronic health information (EHI) IF the request comes from a third party that isn't a provider or a business associate.
 - The Manner exception now includes a condition allowing actors to meet requests using TEFCA provided the requestor is also a TEFCA participant, even if the request indicated they wanted the information provided through other means.

Revised Definition of “Information Blocking”

- Information blocking means a practice that 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; and
 - If conducted by:
 - A health IT developer of certified health IT, health information network or health information exchange, such developer, network or exchange knows, or should know, that such practice is likely to interfere with access, exchange, or use of electronic health information; or

- A health care provider, such provider knows that such practice is unreasonable and is likely to interfere with access, exchange, or use of electronic health information.

“Developer of Certified Health IT” and “Offers Health IT” Definitions

- Developer of certified health IT
 - an individual or entity, other than a health care provider that self-develops health IT for its own use, that develops or offers health information technology and which has, at the time it engages in a practice that is the subject of an information blocking claim, one or more Health IT Modules certified under a program for certification of health by ONC
 - Final rule changed wording to clarify that health care provider that self-develops certified health IT will not be considered a developer of certified health IT if they do not “offer” any certified health IT.
- Offers Health IT:
 - Providing, supplying, or otherwise making available certified health IT under any arrangement or terms except for specifically defined exclusions
 - Final definition narrows potential applicability of health IT developer of certified health IT definition by excluding certain activities from what it means to “offer” health IT
 - Exclusions include:
 - Certain donation and subsidized supply arrangements for obtaining, maintaining or upgrading certified health IT;
 - Common activities associated with purchasing “certified health IT”, such as implementing APIs or portals for clinician or patient access; and
 - Consulting and legal services for administrative management of health care provider.

What makes an actor an “Information Blocker?”

- Actor is any party that meets the definition of a developer of certified health IT or an entity that offers health IT as defined above.
- Must involve Electronic Health Information (EHI)
 - EHI is defined as: electronic protected health information (ePHI) to the extent that the ePHI would be included in a designated record set as defined by HIPAA
 - Applicable whether information is held by a HIPAA covered entity or a non-HIPAA covered entity
 - Exemption: psychotherapy notes in anticipation of, or for use in, a civil, criminal, or administrative action/proceeding
- Practice interferes with or is likely to interfere with appropriate access, use, or exchange of EHI
- Requires requisite knowledge by the actor
- Practice is not mandated by existing law

- Practice is not covered by an exemption in the regulation

Information Blocking “Knowledge Standard”

- Requisite knowledge has a different standard for healthcare providers and Health IT developers
 - Healthcare Providers must “know that a practice is UNREASONABLE and is likely to interfere with the access, exchange, or use” of EHI
 - Health IT developers must “KNOW OR SHOULD KNOW that such a practice is likely to interfere with the access exchange or use” of EHI

New and Revised Information Blocking Exceptions

- Infeasibility
 - Uncontrollable Events
 - Complying with a request for access, exchange or use of EHI would be considered infeasible due to unforeseeable or unavoidable events (e.g. public health emergency, etc.)
 - Final rule clarifies that the event must be the direct cause related to inability to fulfill the request.
 - Third Party Seeking Modification Use Condition
 - The actor is asked to enable a third party to modify EHI that is maintained by or for an entity that deployed health IT and uses EHI. This permits actors to deny requests to modify EHI, if the request is not from a health provider where the actor is the business associate.
- Required Procedures to Fulfill Requests
 - Manner Exception Exhausted
 - “The new ‘manner exception exhausted’ 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.” ([ONC](#))
 - TEFCA Manner Exception
 - This exception applies when the practice follows these conditions:
 - Actor and requestor are both part of TEFCA;
 - The requestor is capable of access, exchange, or use of the requested EHI from the actor via TEFCA;
 - The request is not via an API; and
 - Any fees charged by the actor and the terms for any license of interoperability elements granted by the actor relating to fulfilling the request are required to satisfy, respectively, the Fees Exception and the Licensing Exception.