

**21ST CENTURY CURES ACT:
INTEROPERABILITY, INFORMATION BLOCKING, AND
THE ONC HEALTH IT CERTIFICATION PROGRAM PROPOSED RULE**



Information Blocking Exception for the Licensing of Interoperability Elements on Reasonable and Non-discriminatory Terms

OVERVIEW

Under the proposed exception, it will not be information blocking for an actor to interfere with the access, exchange, or use of electronic health information (EHI) by limiting access to an interoperability element, so long as the interoperability element is available for use by those that need it on reasonable and non-discriminatory terms.

To qualify for this exception, an actor must demonstrate that it:

Timely responded to persons requesting to license or use an interoperability element

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Offered an appropriate license with reasonable and non-discriminatory terms

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Met additional requirements relating to the provision of interoperability elements

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Complied with relevant conditions of certification

“Interoperability Element” is broadly defined to include:

- Any functional element of health IT, whether hardware or software, that could be used to access, exchange, or use EHI for any purpose;
- Any technical information that describes the functional elements (such as a standard, specification, protocol, data model, or schema) that a person of ordinary skill in the art may require to use the functional elements;
- Any technology or service that may be required to enable the use of a compatible technology in production environments; and
- Any license, right, or privilege that may be required to commercially offer and distribute compatible technologies and make them available for use in production environments.

Objective



Intellectual Property (IP) rights can be misused in ways that undermine the promotion of competition and innovation. The potential for abuse is heightened when the IP rights pertain to functional aspects of health IT that are essential to enabling interoperability.

An actor that controls a functional element of health IT that could be used to access, exchange, or use EHI should make that interoperability element available to others that need it, but can impose reasonable and non-discriminatory terms when doing so.

“Actors” regulated by the information blocking provision:



- Health Care Providers
- Health IT Developers of Certified Health IT
- Health Information Exchanges
- Health Information Networks

An actor will not implicate the information blocking provision, and does not need to make an interoperability element available on reasonable and non-discriminatory terms, in circumstances where the entity requesting to license or use the interoperability element is not seeking to use the interoperability element to interoperate with either the actor or the actor’s customers.

Timely Response

Upon receiving a request to license or use interoperability elements, the actor must respond to the requestor within 10 business days from receipt of the request by:

- (1) Negotiating with the requestor in a reasonable and non-discriminatory fashion to identify the interoperability elements that are needed; and
- (2) Offering an appropriate license with reasonable and non-discriminatory terms.

Reasonable and Non-discriminatory License

A reasonable and non-discriminatory license:

- Provides all rights necessary to access and use interoperability elements for the purpose of (as applicable):
 - Developing products or services that are interoperable with the actor's health IT, health IT under the actor's control, or any third party who currently uses the actor's interoperability elements to interoperate with the actor's health IT or health IT under the actor's control;
 - Marketing, offering, and distributing interoperable products or services to potential customers and users; and
 - Enabling the use of interoperable products or services in production environments.
- Imposes no more than a reasonable royalty for use of the interoperability elements, with such royalty being:
 - Non-discriminatory;
 - Based solely on the independent value of the actor's technology to the licensee's products; and
 - If applicable, consistent with the policies of the standards development organization through which it was licensed.
- Contains terms that are objective, verifiable, and uniformly applied, and are not based on whether the requestor is a competitor or the revenue the requestor may derive from the EHI obtained via the interoperability element.
- Must not contain collateral terms that are anti-competitive, including:
 - Certain non-compete or exclusive dealing requirements;
 - Conditioning access to the interoperability element on the purchase of additional licenses, products, or services that are not related to or can be unbundled from the requested interoperability element(s);
 - Requiring the licensee to license, grant, assign, or transfer to the actor any of the licensee's intellectual property; and
 - Obliging the payment of a fee that is not a reasonable royalty and does not meet the requirements of the exception at § 171.204 for the recovery of costs reasonably incurred.
- Must not contain non-disclosure obligations that are broader than necessary to protect trade secrets.

Additional Requirements

To qualify for this exception, the actor must not engage in any practice that has any of the following purposes or effects:

- Impeding the efficient use of the interoperability elements to access, exchange, or use EHI for any purpose for which a person is authorized, permitted, or required to access, exchange, or use the EHI under applicable law;
- Impeding the efficient development, distribution, deployment, or use of an interoperable product or service for which there is actual or potential demand; or
- Making changes to interoperability elements or health IT that "break" compatibility or otherwise degrade the performance of the licensee's compatible technologies or services, unless the actor has afforded the licensee a reasonable opportunity to update its technologies or services to maintain interoperability.

Compliance with Conditions of Certification

If an actor's health IT is subject to the Conditions of Certification at §§ 170.402 (Assurances), 170.403 (Communications), or 170.404 (Application Programming Interfaces), the actor must, for all practices seeking qualification under this exception, and at all relevant times, comply with all requirements of such conditions.