

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

Information Blocking Exception for Requests that are Infeasible



OVERVIEW

Under the proposed exception, it will not be information blocking for an actor to interfere with access, exchange, or use of electronic health information (EHI) because:

- The actor is unable to comply with a request to provide or facilitate access, exchange, or use of EHI; or
- The actor could only comply with the request by incurring costs or other burdens that are clearly unreasonable.

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

Complying with a request to access, exchange,
or use EHI would impose a substantial burden on the
actor that is unreasonable under the circumstances

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The actor timely responded to the request

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The actor worked with the requestor to
identify and provide a reasonable alternative

Objective



Legitimate practical challenges beyond an actor's control may limit its 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, financial resources, or other means necessary to provide a particular form of access, exchange, or use.

The proposed exception should not recognize burdens that relate primarily to an actor's pursuit of an economic advantage.

“Actors” regulated by the information blocking provision:



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

Substantial Burden

The following matters are taken into consideration when assessing whether complying with a request imposes a substantial burden on the actor that is unreasonable:

- The type of EHI and the purposes for which it may be needed;
- The cost to the actor of complying with the request in the manner requested;
- The financial, technical, and other resources available to the actor;
- Whether the actor provides comparable access, exchange, or use to itself or to its customers, suppliers, partners, and other persons with whom it has a business relationship;
- Whether the actor owns or has control over a predominant technology, platform, health information exchange, or health information network through which EHI is accessed or exchanged; and
- Whether the actor maintains electronic protected health information on behalf of a covered entity, or maintains EHI on behalf of the requestor or another person whose access, exchange, or use of EHI will be enabled or facilitated by the actor's compliance with the request.

The burden imposed on the actor is balanced against the countervailing costs to the requestor and other persons who would be harmed by the actor's refusal to provide the requested access, exchange, or use of EHI. This would include considering:

- Whether the requestor and other relevant persons can reasonably access, exchange, or use the EHI from other sources or through other means; and
- The additional cost and burden to the requestor and other relevant persons of relying on alternative means of access, exchange, or use.

A fact-based assessment ensures that the exception is sensitive to the financial and technical resources of an actor, as well the extent of any dependence or reliance placed on an actor to facilitate access, exchange, or use of EHI.

Timely Response and Cooperation

For any request that an actor claims is infeasible, the actor must:

- Provide the requestor with a detailed written explanation of why the actor could not accommodate the request; and
- Work with the requestor in a timely manner to identify and provide a reasonable alternative means of accessing, exchanging, or using the EHI, as applicable.

The sufficiency of the cooperation given is assessed from the standpoint of what is objectively reasonable for an individual or entity in the actor's position.