

Condition of Certification: Information Blocking Fact Sheet

This fact sheet discusses the requirements of the new Information Blocking Condition of Certification for health IT developers (individual or entity), other than a healthcare provider that self-develops health IT for its own use. Certified Health IT Developers are entities that develop or offer health information technology with one or more Health IT Modules certified under the ONC Health IT Certification Program (Certification Program). Conditions and Maintenance of Certification requirements express initial and ongoing requirements that Certified Health IT Developers and their Certified Health IT Module(s) must meet or adhere to in order to maintain their certification status in the Certification Program.

What is information blocking?

In general, information blocking is a practice, except as required by law or covered by a regulatory exception, that is likely to interfere with the access, exchange, or use of electronic health information (EHI). As part of the Conditions of Certification requirement, Certified Health IT Developers cannot engage in information blocking with respect to either their certified or non-certified products. There are no accompanying Maintenance of Certification requirements beyond not engaging in information blocking.

According to the 21st Century Cures Act, information sharing is the law. For the purposes of meeting the Information Blocking Condition of Certification requirement, Certified Health IT Developers are expected to be proactive in avoiding any practice that could be construed as information blocking, even if the practice is connected to the developer's non-certified products or services.

For more information please visit www.healthit.gov/curesrule and review the Final Rule, fact sheets, previously recorded webinars, and all additional resources available on our website such as the Certification Companion Guides with additional information designed to assist Health IT Developers.

When does the information blocking requirement take effect?

Starting on April 5, 2021, any information blocking practice by a Certified Health IT Developer will violate this Condition of Certification. Additionally, these developers must submit attestations to compliance with this and other Conditions and Maintenance of Certification requirements beginning on April 1, 2022, and every six months thereafter.

What are the information blocking exceptions?

Information sharing is the law. However, in the ONC Cures Act Final Rule, ONC identified **eight categories of reasonable and necessary activities** that do not constitute information blocking, provided certain conditions are met. These are referred to as information blocking exceptions.

The exceptions support seamless and secure access, exchange, and use of EHI, and offer Certified Health IT Developers the certainty that these practices will not be considered information blocking if the developer meets the conditions of the exception(s).

- **Preventing Harm Exception:** It will not be information blocking for a Certified Health IT Developer to engage in practices that are reasonable and necessary to prevent harm to a patient or another person, provided certain conditions are met.
- **Privacy Exception:** It will not be information blocking if a Certified Health IT Developer does not fulfill a request to access, exchange, or use EHI in order to protect an individual's privacy, provided certain conditions are met.
- **Security Exception:** It will not be information blocking for a Certified Health IT Developer to interfere with the access, exchange, or use of EHI in order to protect the security of EHI, provided certain conditions are met.
- **Infeasibility Exception:** It will not be information blocking if a Certified Health IT Developer does not fulfill a request to access, exchange, or use EHI due to the infeasibility of the request, provided certain conditions are met.
- **Health IT Performance Exception:** It will not be information blocking for a Certified Health IT Developer to take reasonable and necessary measures to make health IT temporarily unavailable or to degrade the health IT's performance for the benefit of the overall performance of the health IT, provided certain conditions are met.
- **Content and Manner Exception:** It will not be information blocking for a Certified Health IT Developer to limit the content of its response to a request to access, exchange, or use EHI or the manner in which it fulfills a request to access, exchange, or use EHI, provided certain conditions are met.
- **Fees Exception:** It will not be information blocking for a Certified Health IT Developer to charge fees, including fees that result in a reasonable profit margin, for accessing, exchanging, or using EHI, provided certain conditions are met.
- **Licensing Exception:** It will not be information blocking for a Certified Health IT Developer to license interoperability elements for EHI to be accessed, exchanged, or used, provided certain conditions are met.

For more information on the conditions to be met in these exceptions, please visit <https://www.healthit.gov/topic/information-blocking> and review the exceptions' full text in the regulations **45 CFR part 171**

What happens if a developer engages in information blocking?

Certified Health IT Developers found to have committed information blocking may be subject to termination of their certification for Health IT Modules, a certification ban, and could be subject to civil monetary penalties up to \$1 million per violation.