



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

Seven Exceptions to the Information Blocking Provision

OVERVIEW

- ★ Section 4004 of the Cures Act authorizes the Secretary of Health and Human Services to identify reasonable and necessary activities that do not constitute information blocking.
- ★ In consultation with stakeholders, we have identified seven categories of practices that would be reasonable and necessary, provided certain conditions are met.
- ★ The seven categories of reasonable and necessary practices, and their corresponding conditions, are defined through the exceptions proposed at 45 CFR 171.201–207.
- ★ If the actions of a regulated actor (health care provider, health IT developer, or health information exchange or network) satisfy one or more exception, the actions would not be treated as information blocking and the actor would not be subject to civil penalties and other disincentives under the law.

“Actors” regulated by the information blocking provision:



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

§ 171.201 Exception | Preventing Harm

[Read more about the exception for Practices that Prevent Harm \[PDF\]](#)

- An actor may engage in practices that are reasonable and necessary to prevent physical harm to a patient or another person.
- The actor must have a reasonable belief that the practice will directly and substantially reduce the likelihood of physical harm to a patient or another person.
- The practice must implement an organizational policy that meets certain requirements or must be based on an individualized assessment of the risk in each case.

This proposed exception acknowledges that the public interest in protecting patients and other persons against unreasonable risks of harm can justify practices that are likely to interfere with access, exchange, or use of electronic health information (EHI).

§ 171.202 Exception | Promoting the Privacy of EHI

[Read more about the exception for Privacy-Protective Practices \[PDF\]](#)

- An actor may engage in practices that protect the privacy of EHI.
- An actor must satisfy at least one of four discrete sub-exceptions that address scenarios that recognize existing privacy laws and privacy-protective practices: (1) practices that satisfy preconditions prescribed by privacy laws; (2) certain practices not regulated by HIPAA but which implement documented and transparent privacy policies; (3) practices that are specifically permitted under HIPAA; (4) practices that give effect to an individual's privacy preferences.
- The information blocking provision will not require that actors provide access, exchange, or use of EHI in a manner that is not permitted under the HIPAA Privacy Rule.
- General conditions apply to ensure that practices are tailored to the specific privacy risk or interest being addressed and implemented in a consistent and non-discriminatory manner.

This proposed exception would advance the goal of preventing information blocking for improper or self-interested purposes while maintaining and upholding the privacy rights that patients now have.

§ 171.203 Exception | Promoting the Security of EHI

[Read more about the exception for Security-Related Practices \[PDF\]](#)

- An actor may implement measures to promote the security of EHI.
- The practice must be directly related to safeguarding the confidentiality, integrity, and availability of EHI.
- The practice must be tailored to specific security risks and must be implemented in a consistent and non-discriminatory manner.
- The practice must implement an organizational security policy that meets certain requirements or must be based on an individualized determination regarding the risk and response in each case.

This proposed exception would protect actors who mitigate security risks and implement appropriate safeguards to secure the EHI they control.

§ 171.204 Exception | Recovering Costs Reasonably Incurred

[Read more about the exception for Recovering Costs Reasonably Incurred \[PDF\]](#)

- An actor may recover costs that it reasonably incurs, in providing access, exchange, or use of EHI.
- Fees must be: (1) charged on the basis of objective and verifiable criteria uniformly applied to all similarly situated persons and requests; (2) related to the costs of providing access, exchange, or use; and (3) reasonably allocated among all customers that use the product/service.
- Fees must not be based on anti-competitive or other impermissible criteria.
- Certain costs would be specifically excluded from coverage under this exception, such as costs that are speculative or subjective, or costs associated with electronic access by an individual to their EHI.

This proposed exception acknowledges that actors should be able to recover costs that they reasonably incur to develop technologies and provide services that enhance interoperability and promote innovation, competition, and consumer welfare.

§ 171.205 Exception | Responding to Requests that are Infeasible

[Read more about the exception for Requests that are Infeasible \[PDF\]](#)

- An actor may decline to provide access, exchange, or use of EHI in a manner that is infeasible.
- Complying with the request must impose a substantial burden on the actor that is unreasonable under the circumstances (taking into account the actor's size, resources, etc.).
- The actor must timely respond to infeasible requests and work with requestors to provide a reasonable alternative means of accessing the EHI.

This proposed exception acknowledges that there may be legitimate practical challenges beyond an actor's control that may limit its ability to comply with requests for access, exchange, or use of EHI.

§ 171.206 Exception | Licensing of Interoperability Elements on Reasonable and Non-discriminatory Terms

[Read more about the exception for the Licensing of Interoperability Elements on Reasonable and Non-discriminatory Terms \[PDF\]](#)

- An actor that controls technologies or other interoperability elements that are necessary to enable access to EHI will not be information blocking so long as it licenses such elements on reasonable and non-discriminatory terms.
- The license can impose a reasonable royalty but must include appropriate rights so that the licensee can develop, market, and/or enable the use of interoperable products and services.
- The terms of the license must be based on objective and verifiable criteria that are uniformly applied and must not be based on impermissible criteria, such as whether the requestor is a potential competitor.

This proposed exception would allow actors to protect the value of their innovations and earn returns on the investments they have made to develop, maintain, and update those innovations.

§ 171.207 Exception | Maintaining and Improving Health IT Performance

[Read more about the exception for Practices that Maintain and Improve Health IT Performance \[PDF\]](#)

- An actor may make health IT under its control temporarily unavailable in order to perform maintenance or improvements to the health IT.
- An actor must ensure that the health IT is unavailable for no longer than necessary to achieve the maintenance or improvements.
- In circumstances when health IT is supplied to an individual or entity, the individual or entity (e.g., customer) must agree to the unavailability of health IT.

The proposed exception recognizes that it may be reasonable and necessary for actors to make health IT, and in turn EHI, temporarily unavailable for the benefit of the overall performance of health IT.