



21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Proposed Rule

Information Blocking

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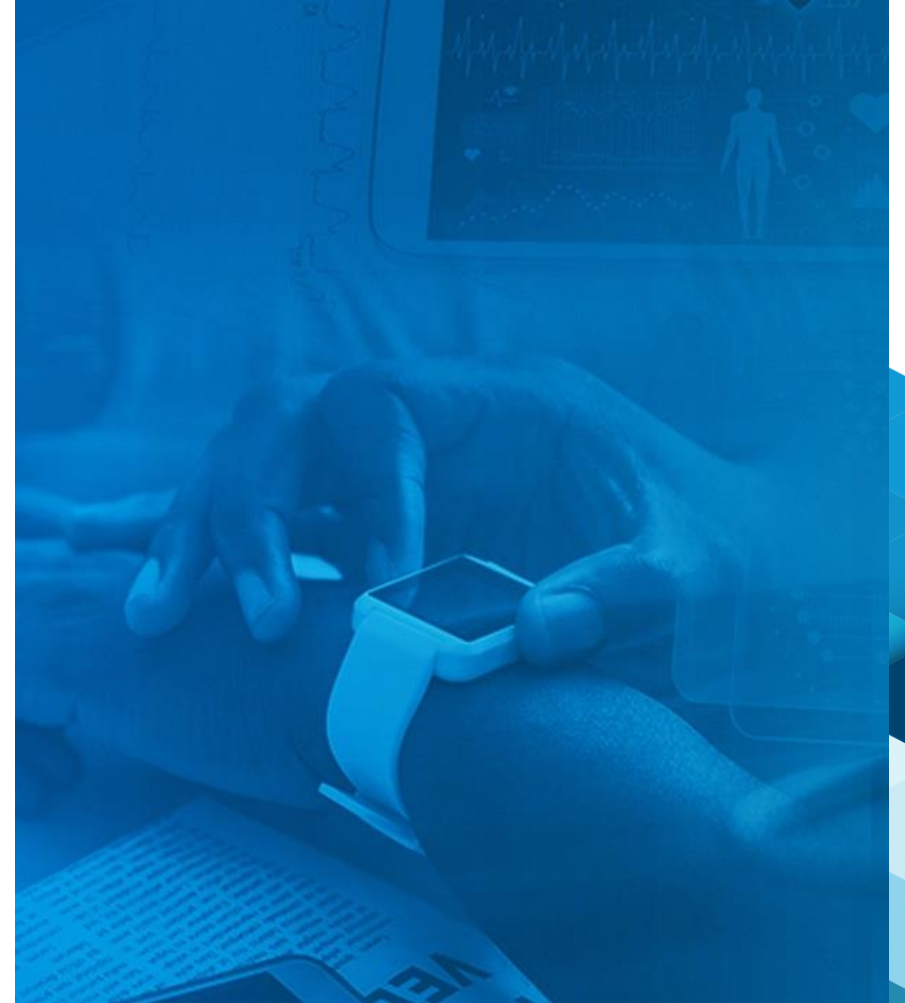


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Information Blocking

- A. Background
- B. Relevant Statutory Terms and Provisions
& Comments Received
- C. Proposed Exceptions & Comments
Received





Background

Information Blocking – Path to the 21st Century Cures Act



In a 2015 report to Congress, ONC provided a definition of information blocking, an analysis of the extent to which the practice exists in the industry, and recommendations to address the issue.



ONC continued to engage with stakeholders and provided ongoing technical assistance to Congress.



In December 2016, the 21st Century Cures Act was signed into law. It included a definition of information blocking and provisions for addressing information blocking.

Information Blocking in the 21st Century Cures Act

21st Century Cures Act, Section 4004:

- Defines “information blocking” (§ 3022(a)(1), PHSA).
- Authorizes the Secretary to identify, through rulemaking, reasonable and necessary activities that do not constitute information blocking (§ 3022(a)(3), PHSA).
- Identifies the HHS Office of Inspector General (OIG) as the HHS office to investigate claims of information blocking (§ 3022(b)(1), PHSA) and provides referral processes to facilitate coordination with the HHS Office for Civil Rights (OCR) (§ 3022(b)(3)(A), PHSA).
- Prescribes penalties for information blocking (§ 3022(b)(2), PHSA).
- Charges ONC with implementing a complaint process for reporting information blocking, and provides confidentiality protections for complaints (§ 3022(d)(2) and (3), PHSA).



Information Blocking Definition in the Cures Act

[T]he term “**information blocking**” means a practice that—

(A) except as required by law or specified by the Secretary pursuant to rulemaking under paragraph (3), is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information; and

(B) (i) if conducted by a **health information technology developer, exchange, or network**, such developer, exchange, or network **knows**, or **should know**, that such practice is likely to interfere with, prevent, or materially discourage the access, exchange, or use of electronic health information; or

(ii) if conducted by a **health care provider**, such provider **knows** that such practice is **unreasonable** and is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information.



What Makes an Individual or Entity an Information Blocker?

Elements of information blocking

- ☐ Actor regulated by the information blocking provision
- ☐ Involves electronic health information (EHI)
- ☐ Practice is likely to interfere with, prevent, or materially discourage access, exchange, or use of EHI
- ☐ Requisite knowledge by the actor
- ☐ Not required by law
- ☐ Not covered by an exception



Consequences of Being an Information Blocker

- **Cures Act prescribes penalties for information blocking (§ 3022(b)(2), PHSA)**
 - Health IT developers, networks, and exchanges → Civil monetary penalty up to \$1 million per violation
 - Healthcare providers → Appropriate disincentives
- **ONC proposed a certification ban (§ 170.581) for health IT developers in violation of the Conditions of Certification**
 - Information blocking Condition of Certification (proposed § 170.401)
 - Public listing of certification bans and terminations
- **CMS proposed public reporting of clinicians and hospitals who submit a “no” response to attestation statements related to information blocking**

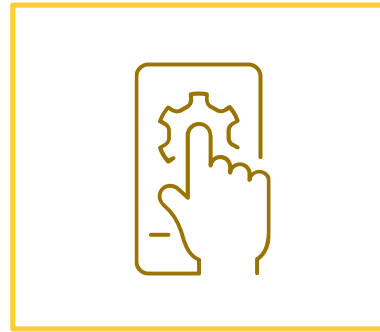


Relevant Statutory Terms and Provisions & Comments Received

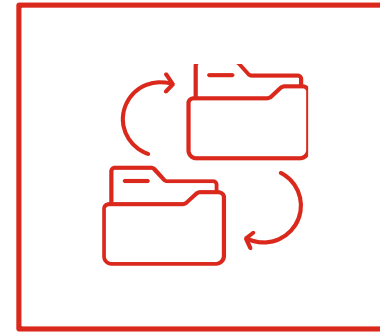
“Actors” Regulated by the Information Blocking Provision



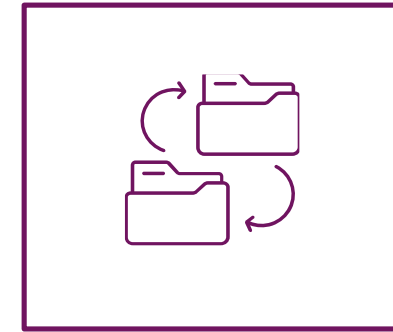
**Health Care
Providers**



**Health IT
Developers of
Certified Health IT**



**Health
Information
Networks (HIN)**



**Health
Information
Exchanges (HIE)**



Health Care Providers

Who are they?

- a hospital
- skilled nursing facility
- nursing facility
- home health entity or other long term care facility
- health care clinic
- community mental health center
- renal dialysis facility
- blood center
- ambulatory surgical
- emergency medical services provider
- federally qualified health center
- group practice
- a pharmacist
- a pharmacy
- a laboratory
- a physician
- a practitioner
- a rural health clinic
- an ambulatory surgical center
- a provider operated by, or under contract with, the Indian Health Service or by an Indian tribe, tribal organization, or urban Indian organization
- a “covered entity” under certain statutory provisions
- a therapist
- any other category of health care facility, entity, practitioner, or clinician determined appropriate by the Secretary

Comments

Some favored the HIPAA definition. Others noted that using the HIPAA definition might be overly broad.

Health IT Developer of Certified Health IT

Who are they?

An individual or entity that develops or offers health information technology and which had, at the time it engaged in a practice that is the subject of an information blocking claim, health IT (one or more) certified under the Program.

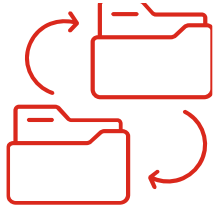


Comments

- Much support for the definition.
- Recommended we cover all developers of health IT under the definition, whether or not their products were *certified* under ONC's Health IT Certification Program. Concern that if all developers are not covered, rules will not be the same for everyone.
- Request to narrow definition so it only focuses on conduct related to certified products.

Health Information Networks & Exchanges

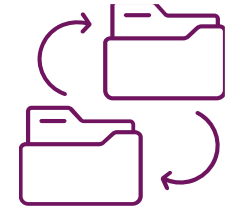
Health Information Network



An individual or entity that satisfies one or both of the following—

- Determines, oversees, administers, controls, or substantially influences policies or agreements that define business, operational, technical, or other conditions or requirements for enabling or facilitating access, exchange, or use of EHI between or among two or more unaffiliated individuals or entities.
- Provides, manages, controls, or substantially influences any technology or service that enables or facilitates the access, exchange, or use of EHI between or among two or more unaffiliated individuals or entities.

Health Information Exchange



An individual or entity that enables access, exchange, or use of EHI primarily between or among a particular class of individuals or entities or for a limited set of purposes.

Comments - Noted overlap in the two definitions and suggested we consider combining them.

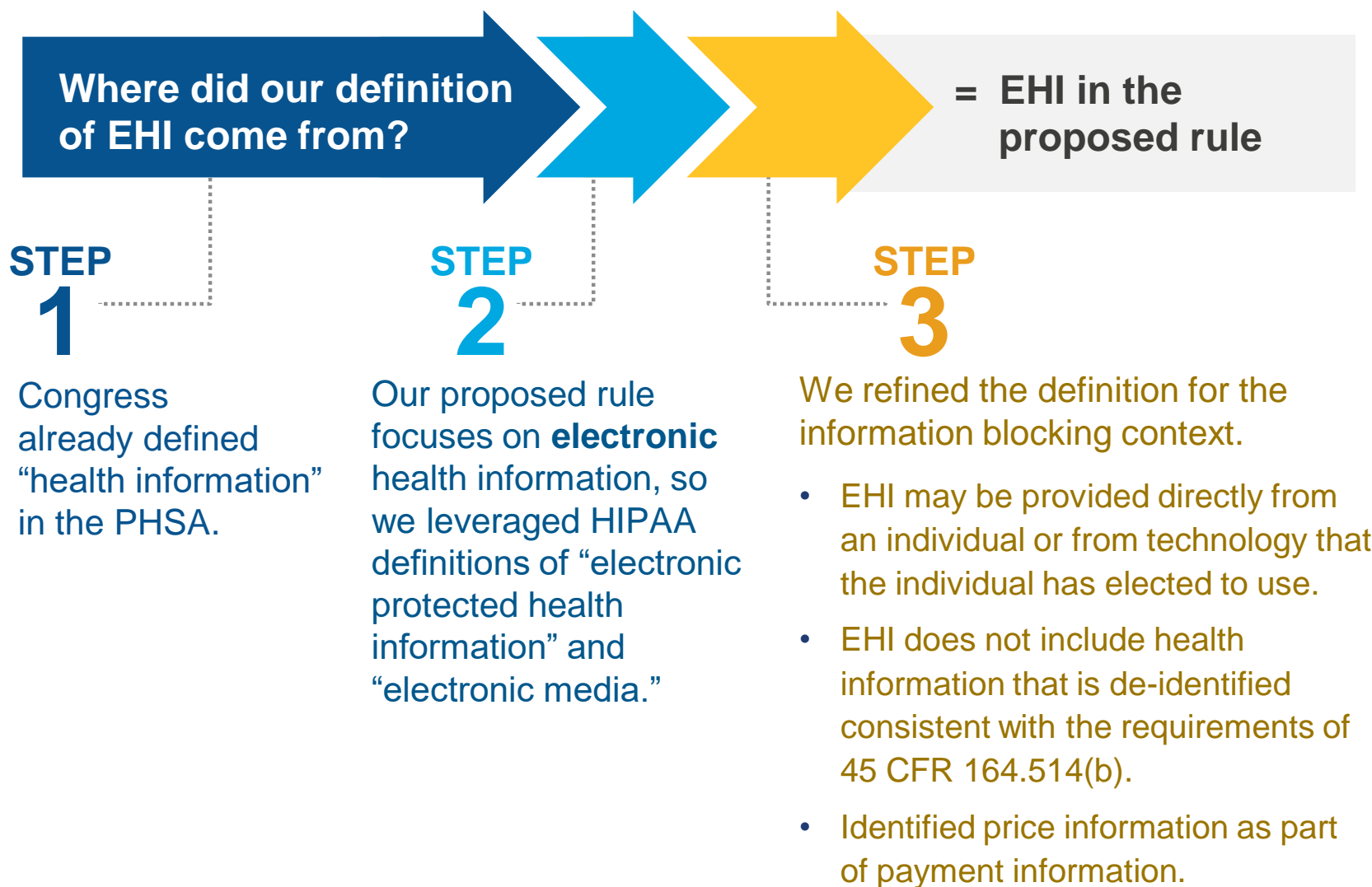
Electronic Health Information

We proposed to define electronic health information (EHI) to mean electronic protected health information (as defined in HIPAA), and any other information that:

- is transmitted by or maintained in electronic media (as defined in 45 CFR 160.103);
- identifies the individual, or with respect to which there is a reasonable basis to believe the information can be used to identify the individual; and
- relates to the past, present, or future health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual.



Electronic Health Information



Comments

- Mixed response over the EHI definition generally.
- Some supported it as proposed and agreed with the breadth, but others thought it was too vague.
- Concern about differentiating between EHI and ePHI.
- Other proposals were ePHI, observational health information, and standardized health information.

Price Information

- **Request for Comment:** We sought comment on the parameters and implications of including price information within the scope of EHI for purposes of information blocking.
- **Requests for Information:** Consistent with its statutory authority, the Department is considering subsequent rulemaking to expand access to price information for the public, prospective patients, plan sponsors, and health care providers. The overall Department sought comment on the technical, operational, legal, cultural, environmental and other challenges to creating price transparency within health care.
- **Comments: Over 1,100 comments received**
 - Including price information in the EHI definition would increase competition and reduce costs.
 - Price information is beyond the scope of the Cures Act and disclosure would harm competition in the health care market.

Interfere with Access, Exchange, or Use

“Interfere with, prevent, or materially discourage”

- The terms “interfere with” and “interference” are used inclusive of prevention, material discouragement, and other forms of interference that implicate the information blocking provision.
- We interpret “interference” broadly and to take many forms.

“Access, exchange, or use”

These concepts are closely related → EHI cannot be **used** unless it can be **accessed**, and this often requires that the EHI be **exchanged** among different individuals or entities and through various technological means.



We proposed to adopt interrelated definitions:

- **“Access”** means the ability or means necessary to make electronic health information available for use, including the ability to securely and efficiently locate and retrieve information from any and all source systems in which the information may be recorded or maintained.
- **“Exchange”** means the ability for EHI to be transmitted securely and efficiently between and among different technologies, systems, platforms, or networks in a manner that allows the information to be accessed and used.
- **“Use”** means the ability of health IT or a user of health IT to access relevant EHI; to comprehend the structure, content, and meaning of the information; and to read, write, modify, manipulate, or apply the information to accomplish a desired outcome or to achieve a desired purpose.

Interfere with Access, Exchange, or Use

Comments

- Support for the proposed definitions.
- Definitions are overly broad.
- Supported use of existing HIPAA definitions.
- Requested additional clarity/examples regarding what would/would not constitute an interference.

Practices that Implicate the Information Blocking Provision

OVERARCHING PRINCIPLE

To **implicate** the provision is not necessarily to **violate** it.

- Imposing formal restrictions on access, exchange, or use of EHI
- Imposing informal restrictions on access, exchange, or use of EHI
- Disabling or restricting the use of a capability that enables users to share EHI with users of other systems
- Implementing capabilities in ways that limit the timeliness of access, exchange, or use of EHI
- Imposing terms or conditions on the use of interoperability elements that discourage their use
- Discouraging efforts to develop or use interoperable technologies or services by exercising influence over customers, users, or other persons
- Discriminatory practices that frustrate or discourage efforts to enable interoperability
- Rent-seeking and opportunistic pricing practices
- Implementing health IT in non-standard ways that substantially increase the complexity or burden of accessing, exchanging, or using EHI (for instance, not complying with section 3004 of the PHSA or consensus standards)

Required by Law

What does it mean?

It refers specifically to interferences with access, exchange, or use of EHI that are explicitly required by state or federal law.

We distinguished between interferences that are “required by law” and those engaged in pursuant to a privacy law, but which are not “required by law.”

Comments

Requests for clarification regarding the meaning and scope of “required by law.”



Proposed Exceptions & Comments Received

Overview of Exceptions

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.

Proposed exceptions to the information blocking definition

- » **171.201** — Preventing harm
- » **171.202** — Promoting the privacy of EHI
- » **171.203** — Promoting the security of EHI
- » **171.204** — Recovering costs reasonably incurred
- » **171.205** — Responding to requests that are infeasible
- » **171.206** — Licensing of interoperability elements on reasonable and non-discriminatory terms
- » **171.207** — Maintaining and improving health IT performance





Exception: Preventing Harm

Overview

Under the proposed exception, it will not be information blocking for an actor to engage in practices that are reasonable and necessary to prevent harm to a patient or another person, provided certain conditions are met.

To qualify for this exception, an actor must:

Have a reasonable belief that the practice will directly and substantially reduce the likelihood of a recognized harm to a patient or another person

**Implement a Qualifying
Organizational Policy**

or

**Implement a Qualifying
Individualized Finding**



Objective

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 EHI. The exception focuses on risks of harm that are specific to access, exchange, or use of EHI.



Exception: Preventing Harm

Comments

- Suggested use of HIPAA standard to deny records access – “life or physical safety.”
- Concern regarding corrupt, incomplete, or erroneous data, and sharing data from third-party sources that may be mismatched across records.
- Request for more information about what the qualifying organizational policies should consider/include.
- Request for materials to clarify how ONC will implement this exception.



Exception: Promoting the Privacy of EHI

Overview

Under the proposed exception, it will not be information blocking for an actor to engage in certain recognized privacy-protective practices that interfere with the access, exchange, or use of EHI, and that are reasonable and necessary.

**To qualify for this exception,
an actor's privacy-protective practice must:**

Satisfy at least one sub-exception

+

**Meet all conditions applicable
to a sub-exception being relied on**



Objective

If an actor is authorized to provide access, exchange, or use of EHI under a privacy law, then the information blocking provision would require that the actor provide that access, exchange, or use of EHI. However, the information blocking provision should not require the use or disclosure of EHI in a way that is prohibited under state or federal privacy laws.



Exception: Promoting the Privacy of EHI

Four Sub-exceptions

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 (e.g., consents and authorizations);
2. Certain practices not regulated by HIPAA but which implement documented and transparent privacy policies;
3. Denial of access practices that are specifically permitted under HIPAA (e.g., 45 CFR § 164.524); or
4. Practices that give effect to an individual's request not to share information (e.g., 45 CFR § 164.522).



Exception: Promoting the Privacy of EHI

Comments

- Business associate should not be liable for IB if allowing access, exchange or use would violate its BAA.
- Request to clarify whether actors that operate in multiple states with different preconditions should be able to implement uniform requirements to satisfy the most stringent preconditions.
- Recommendation that actors should be able to have organization-specific policies that are more restrictive than state/federal law.
- Request to clarify the meaning of doing all things reasonably necessary in actor's control to provide individual with a meaningful opportunity to satisfy a precondition.
- Support for apps being used to access PHI as requested by patients, but concerns about privacy.



Exception: Promoting the Security of EHI

Overview

Under the proposed exception, it will not be information blocking for an actor to engage in practices that interfere with access, exchange, or use of EHI and that are reasonable and necessary to secure EHI, subject to certain conditions.

**To qualify for this exception,
an actor's security-related practice must:**

Satisfy threshold conditions

**Implement a Qualifying
Organizational Security Policy**

or

**Implement a Qualifying
Security Determination**



Objective

Establish an exception that is sufficiently flexible to recognize all legitimate security practices.

To protect reasonable and necessary security practices by actors, but not prescribe a maximum level of security or dictate a one-size-fits-all approach.



Exception: Promoting the Security of EHI

Comments

- Request for additional flexibility in the conditions.
- Sought guidance on how to meet the conditions in practice.
- Request for clarification regarding term like “directly related” or “tailored.”
- Regarding “consensus-based standards,” commentators felt that security threats may evolve and require action more quickly than such standards are issued.



Exception: Recovering Costs Reasonably Incurred

Overview

Under the proposed exception, it will not be information blocking for an actor to recover its reasonable costs of enabling access, exchange, or use of EHI. The proposed exception does not prescribe the amount of fees that can be charged, but imposes conditions to ensure that an actor's method for recovering costs is reasonable and non-discriminatory.

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

Its method for recovering costs complies with certain conditions

+

It is not seeking to recover costs that are specifically excluded

+

It complies with the Conditions of Certification at § 170.402(a)(4) or § 170.404, and the fee limitations imposed on health IT developers of certified health IT, if applicable



Objective

Enable actors to recover the costs reasonably incurred to develop technologies and provide services that enhance interoperability, while not protecting rent-seeking, opportunistic fees, and exclusionary practices that interfere with access, exchange, or use of EHI.

Would **not** prevent an actor from making a profit.



Exception: Recovering Costs Reasonably Incurred

Comments

- Request to clarify the types of fees covered by the exception.
- Request to clarify whether profits are allowed under the exception.
- Concern that this exception will serve as a barrier to innovation, competition, and interoperability.
- Concern about vague wording.
- Request for more guidance and examples.



Exception: Responding to 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 EHI because:

- The actor is unable to comply with a request to provide or facilitate access, exchange, or use; 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

+

The actor timely responded to the request

+

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.



Exception: Responding to Requests that are Infeasible

Comments

- Request to clarify terms used and provide additional guidance.
- Question whether it would be considered information blocking if EHI could not be segmented to comply with other applicable laws.
- Request to specify if prior contractual obligations can serve as a basis for infeasibility, such as conflicts with valid contracts, BAAs, etc.
- Request for clarification regarding what would constitute a reasonable alternative means of accessing EHI.



Exception: 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 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 (RAND) terms.

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

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

+

Offered an appropriate license with RAND terms

+

Met additional requirements relating to the provision of interoperability elements

+

Complied with relevant conditions of certification



Objective

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 RAND terms when doing so.

Complying with this exception would **not** prevent an actor from making a profit.



Exception: Licensing of Interoperability Elements on Reasonable and Non-discriminatory Terms

Comments

- Recommended that ONC require licensors of interoperability elements to publish their standard licensing rate or the license itself.
- Requests for clarification regarding royalty rates and licensing framework, especially regarding “RAND.”
- Concerns about the potential effect of the exception on innovation, competition, and IP rights.
- Requests to revise the response timeframe.



Exception: Maintaining and Improving Health IT Performance

Overview

Under the proposed exception, it will not be information blocking for an actor to interfere with the access, exchange, or use of EHI by making health IT unavailable in order to undertake maintenance or improvements to the health IT, provided certain conditions are met.

To qualify for this exception, the unavailability of health IT for maintenance or improvements must be:

For no longer than necessary to achieve the maintenance or improvements for which the health IT was made unavailable

+

Implemented in a consistent and non-discriminatory manner

+

Agreed to by the individual or entity to whom the health IT is supplied.



Objective

For health IT to perform properly and efficiently, it must be maintained, and in some instances improved. This may require that health IT be taken offline temporarily.

Actors should not be deterred from taking reasonable and necessary measures to make health IT temporarily unavailable for the benefit of the overall performance of health IT.



Exception: Maintaining and Improving Health IT Performance

Comments

- Some commenters agreed that temporary unavailability of health IT “for a period of time no longer than necessary” created an appropriate standard for both planned and unplanned downtimes, while others were concerned that the requirement would be difficult to assess and requested defined time periods.
- Recommendation that we recognize there may be circumstances where a downtime may exceed service level agreements, but still be no longer than necessary to address the issue.
- Request to clarify whether this exception would apply to practices that degrade some aspects of a health IT system’s performance without making it entirely unavailable.



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Questions?



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