Information Blocking:
Answers to Frequently Asked Questions

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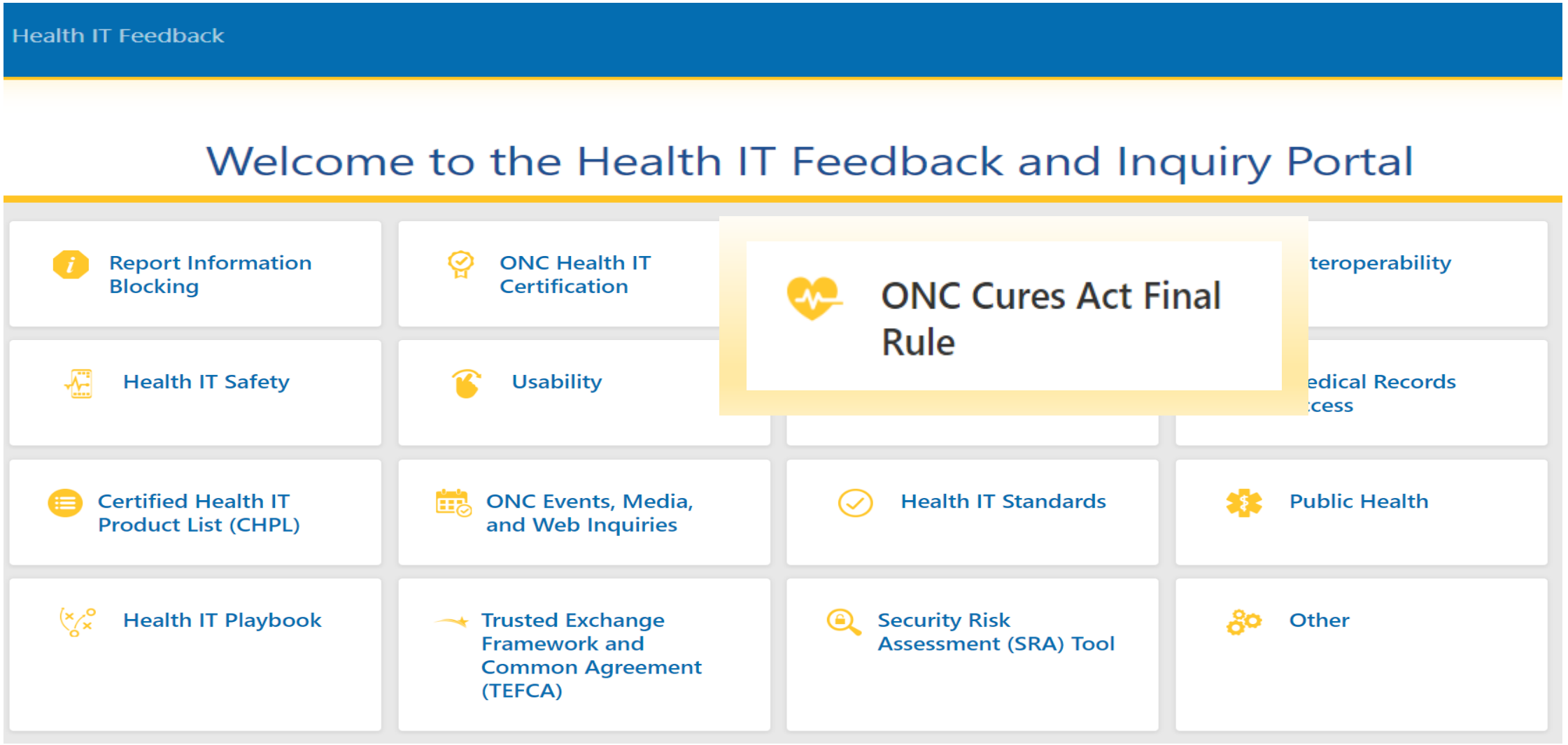

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Information Blocking Definition

(a) Information blocking means a practice that—

(1) Except as required by law or covered by an exception, is likely to interfere with access, exchange, or use of electronic health information (EHI); and

(2) **If conducted by a health information technology developer, health information network or health information exchange**, such developer, network or exchange knows, or should know, that such practice is likely to interfere with access, exchange, or use of EHI; or

(3) **If conducted by a health care provider**, such provider knows that such practice is unreasonable and is likely to interfere with the access, exchange, or use of EHI.

(b) Until date specified in 45 CFR 171.103(b), EHI for purposes of § 171.103(a) is limited to the EHI identified by the data elements ***represented in*** the USCDI standard adopted in § 170.213.

Applicability Dates and EHI

- **On and after April 5, 2021,** an actor must respond to a request to access, exchange, or use EHI with, *at a minimum*, all requested EHI identified by the data elements ***represented in*** the USCDI standard.
- **On and after October 6, 2022**, an actor must respond to a request to access, exchange, or use EHI with **EHI as defined in § 171.102**.

Points of Interest:

- ***Can*** be met if the actor does not have all the requested EHI.
- Does ***not*** require EHI be held in or shared using specific technology or particular technical standards.
- ***Can*** be met where some EHI actor has restricted by law or permissible to withhold, such as consistent with Preventing Harm or Privacy Exception.

Compliance and Enforcement Timeline

- **ONC Health IT Certification Program** - On April 5, 2021, developers of certified health IT will be subject to the "information blocking" condition of certification found in 45 CFR 170.401.

- **Civil Monetary Penalties** - Enforcement of information blocking civil monetary penalties (CMPs) will not begin until established by future rulemaking by OIG. As a result, actors will not be subject to penalties until the CMP rule is final.
    - *At a minimum*, the timeframe for enforcement will **not** begin sooner than the compliance date of the ONC final rule and will depend on when the CMP rules are final.
    - Discretion will be exercised such that conduct that occurs before the CMP rule is final will not be subject to information blocking CMPs.

January 2021 FAQs

Information Blocking FAQs - General

Q: Do the information blocking regulations require actors to have or use certified health IT, or upgrade the certified health IT they already have, in order to fulfill a request to access, exchange, or use electronic health information?

No. The information blocking regulations **do not** require actors to have or use health IT certified under the ONC Health IT Certification Program. Actors subject to the information blocking regulations are not required to immediately upgrade their certified health IT (as of the applicability date (i.e., April 5, 2021)) if they also happen to participate in a separate regulatory program that requires the use of certified health IT, such as CMS' Promoting Interoperability Programs.

Information Blocking FAQs - Interference

Q: Do the information blocking regulations (45 CFR Part 171) require actors to proactively make electronic health information (EHI) available through "patient portals," application programming interfaces (API), or other health information technology?

No. There is no requirement under the information blocking regulations to proactively make available any EHI to patients or others who have **not** requested the EHI. We note, however, that a delay in the release or availability of EHI in response to a request for legally permissible access, exchange, or use of EHI may be an interference under the information blocking regulations (85 FR 25813, 25878). If the delay were to constitute an interference under the information blocking regulations, an actor's practice or actions **may** still satisfy the conditions of an exception under the information blocking regulations (45 CFR 171.200-303).

Information Blocking FAQs - Interference

Q: Are actors (for example, health care providers) expected to release test results to patients through a patient portal or application programming interface (API) as soon as the results are available to the ordering clinician?

While the information blocking regulations do not require actors to proactively make electronic health information (EHI) available, once a request to access, exchange or use EHI is made actors must timely respond to the request (for example, from a patient for their test results). Delays or other unnecessary impediments could implicate the information blocking provisions.

In practice, this could mean a patient would be able to access EHI such as test results in parallel to the availability of the test results to the ordering clinician.

Information Blocking FAQs - Interference

Q: When a state or federal law or regulation, such as the HIPAA Privacy Rule, requires EHI be released by no later than a certain date after a request is made, is it safe to assume that any practices that result in the requested EHI's release within that other required timeframe will never be considered information blocking?

No. The information blocking regulations (45 CFR Part 171) have their own standalone provisions (*see* 42 U.S.C. 300jj-52). The fact that an actor covered by the information blocking regulations meets its obligations under another law applicable to them or its circumstances (such as the maximum allowed time an actor has under that law to respond to a patient's request) will not automatically demonstrate that the actor's practice does not implicate the information blocking definition.

If an actor who could more promptly fulfill requests for legally permissible access, exchange, or use of EHI chooses instead to engage in a practice that delays fulfilling those requests, that practice could constitute an interference under the information blocking regulation, even if requests affected by the practice are fulfilled within a time period specified by a different applicable law.

Information Blocking FAQs - Interference

Q: Is it information blocking when state law requires a specific delay in communication of EHI, or that certain information be communicated to the patient in a particular way, before the information is made available to the patient electronically?

No. The definition of information blocking (45 CFR 171.103) does not include practices that interfere with access, exchange or use of EHI when they are specifically *required* by applicable law (*see* 85 FR 25794). To the extent the actor's practice is likely to interfere with access, exchange, or use of EHI beyond what would be specifically necessary to comply with applicable law, the practice could implicate the information blocking definition.

Information Blocking FAQs – Preventing Harm Exception

Q: Do the Preventing Harm Exception requirements for the type of harm align with the HIPAA Rules?

Yes. The Preventing Harm Exception's *type of harm* condition relies on the same types of harm that serve as grounds for reviewable denial of an individual's right of access under the Privacy Rule (45 CFR 164.524). (*See* ONC Cures Act Final Rule preamble Table 3—Mapping of Circumstances Under § 171.201(d) to Applicable Harm Standards.) In most instances, including where a practice interferes with a patient's own or the patient's other health care providers' legally permissible access, exchange, or use of the patient's electronic health information (EHI), coverage under the Preventing Harm Exception requires that the risk be of physical harm. (*See* 45 CFR 171.201(d)(3) and (4).)

However, the Preventing Harm Exception's *type of harm* condition applies a "substantial harm" standard for practices interfering with a patient's ***representative's*** requested access, exchange, or use of the patient's EHI and to the patient's or their representative's access to other persons' individually identifiable information within the patient's EHI in some circumstances. (*See* 45 CFR 171.201(d)(1) and (2)).

Information Blocking FAQs – Preventing Harm Exception

Q: Will the Preventing Harm Exception cover practices interfering with a patient's access, exchange, or use of their EHI only for the purposes of reducing an imminent or immediate risk of harm?

No. The *reasonable belief* condition does not include a requirement that the harm be expected to occur within a particular time period or that the likelihood of the harm be high enough to be considered "imminent." (*See* 45 CFR 171.201(a)). The Preventing Harm Exception's *reasonable belief* condition requires an actor engaging in a practice likely to interfere with a patient's access, exchange, or use of their own EHI to have a reasonable belief that the practice will substantially reduce a risk to life or physical safety of the patient or another person that would otherwise arise from the affected access, exchange, or use.

Information Blocking FAQs – Preventing Harm Exception

Q: Would the Preventing Harm Exception cover a "blanket" several day delay on the release of laboratory or other test results to patients so an ordering clinician can evaluate each result for potential risk of harm associated with the release?

(1/2) No. Blanket delays that affect a broad array of routine results do not qualify for the Preventing Harm Exception. The Preventing Harm Exception is designed to cover only those practices that are no broader than necessary to reduce a risk of harm to the patient or another person.
As we discussed in the Cures Act Final Rule, a clinician generally orders tests in the context of a clinician-patient relationship. In the context of that relationship, the clinician ordering a particular test would know the range of results that could be returned and could prospectively formulate, in the exercise of their professional judgment, an individualized determination for the specific patient that:

- witholding the results of the particular test(s) from the patient would substantially reduce a risk to the patient's or another person's life or physical safety ***- or -***
- that witholding the results of the particular test(s) from a representative of the patient would substantially reduce a risk of substantial harm to the patient or another person.

Information Blocking FAQs – Preventing Harm Exception

(continued) Q: Would the Preventing Harm Exception cover a "blanket" several day delay on the release of laboratory or other test results to patients so an ordering clinician can evaluate each result for potential risk of harm associated with the release?

(2/2) Such individualized determinations made in good faith by an ordering clinician, in the exercise of their professional judgment and in the context of the treatment relationship within which they order the test, would satisfy the *type of risk* and *type of harm* conditions of the Preventing Harm Exception. Actors, including but not limited to the ordering clinician, could implement practices in reliance on such determinations and the Preventing Harm Exception would cover such practices so long as the practices also satisfy the other four conditions of the exception.

Information Blocking FAQs – Preventing Harm Exception

Q: Where the patient is a minor and to avoid breaching the patient's confidentiality and trust with the provider, will the Preventing Harm exception cover an actor's practices that interfere with a parent or legal representative's access, exchange, or use of the minor's EHI?

No. Unless an actor reasonably believes a practice that interferes with a parent or other legal representative's requested access, exchange, or use of the minor's electronic health information (EHI) will substantially reduce a risk of at least substantial harm to the patient or another person, the Preventing Harm Exception is not designed to cover that practice.

The Privacy Exception contains a sub-exception (45 CFR 171.202(e)) that covers practices respecting an individual's request not to share information, subject to certain conditions.

Information Blocking FAQs – Preventing Harm Exception

Q: Where the patient is a minor and to reduce a risk of harm other than physical abuse, will the Preventing Harm Exception cover an actor's practices that interfere with a parent or legal guardian's access, exchange, or use of the minor's EHI?

(1*/*2) Yes, where the *risk of harm* has been determined on an individualized basis and all other conditions of the Preventing Harm Exception are met. For example, the practice must be no broader than necessary and the actor must reasonably believe the practice will substantially reduce the risk of harm. (For all the conditions of the Preventing Harm Exception, please see 45 CFR 171.201.)

For purposes of the Preventing Harm Exception, a parent or legal guardian would be considered a patient's legal representative. The Preventing Harm Exception's *type of harm* condition applies a "substantial harm" standard for practices interfering with a patient's ***representative's*** requested access, exchange, or use of the patient's EHI. (*See* 45 CFR 171.201(d)(1)).

Information Blocking FAQs – Preventing Harm Exception

(continued) Q: Where the patient is a minor and to reduce a risk of harm other than physical abuse, will the Preventing Harm Exception cover an actor's practices that interfere with a parent or legal guardian's access, exchange, or use of the minor's EHI?

(2/2) The *type of harm* conditions for Preventing Harm Exception coverage of practices interfering with patients' and their representatives' access to EHI on the basis of an individualized determination of risk are specifically aligned with the HIPAA Privacy Rule's grounds for reviewable denial of an individual's right of access under the Privacy Rule. (*See also* ONC Cures Act Final Rule preamble discussion and Table 3—Mapping of Circumstances Under § 171.201(d) to Applicable Harm Standards).

Questions