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Interference

Q: Do the information blocking regulations (45 CFR Part 171) require actors to make patients aware of newly available electronic health information (EHI)? (IB.FAQ44.1.2022FEB)

A: There is no specific regulatory provision under the information blocking regulations that expressly requires actors to make individuals aware of newly available EHI, whether from a recent clinical encounter or newly available historical EHI not previously accessible to a patient. In most circumstances, practices to notify patients (e.g., by text alert or email) about newly available EHI or stopping such notifications would likely *not* be considered information blocking.

Please see the following FAQ for more information on how practices would be evaluated to determine whether the unique facts and circumstances constitute information blocking: **Q: How would any claim or report of information blocking be evaluated? (IB.FAQ46.1.2022FEB)**

Q: Can an actor grant a patient's request to delay the release of a patient's test result(s) (e.g., laboratory or image result(s)) to the patient without implicating the information blocking regulations? (IB.FAQ45.1.2022FEB)

A: It would likely *not* be an interference when an actor follows an individual patient's, or patient's representative's, request to delay release of the patient's electronic health information (EHI) to the patient or to the patient's representative.
In the preamble to the 21st Century Cures Act final rule, we recognized that "some delays may be legitimate" (85 FR 25813) and not an interference (as defined in 45 CFR 171.102). However, the unique facts and circumstances of each situation would need to be evaluated. Generally, a delay should be for no longer than necessary to fulfill each patient's request (see 85 FR 25813; see also 85 FR 25878 and 45 CFR 171.301(b)(2)(i)).
When assessing whether a delay may be information blocking, facts indicating that an actor created extended or unnecessary delays may be evidence of an actor's intent to interfere with, prevent, or materially discourage access, exchange, or use of EHI (85 FR 25813). For example, when an actor delays the release of EHI in response to a patient's request, relevant considerations for assessing whether the delay may be information blocking could include, without limitation, whether: the patient and actor agree on the timeframe or conditions for the delay (e.g., after 3 days or upon their clinician's review, respectively), the timeframe or conditions are met, and there were no extended or unnecessary delays in meeting the timeframe or conditions.
Please see the following FAQ for more information on how practices would be evaluated to determine whether the unique facts and circumstances constitute information blocking: **Q: How would any claim or report of information blocking be evaluated? (IB.FAQ46.1.2022FEB)**

Please also see the following FAQ regarding when a delay in making EHI available through a "patient portal" or an application programming interface (API) for patients could constitute an interference and thus implicate the information blocking regulations: **Q: When would a delay in fulfilling a request for access, exchange, or use of EHI be considered an interference under the information blocking regulation? (IB.FAQ22.1.2021MAR)**

Q: Would not complying with another law implicate the information blocking regulations? (IB.FAQ43.1.2022FEB)

A: If an actor is required to comply with another law that relates to the access, exchange, or use of EHI (as defined in 45 CFR 171.102), failure to comply with that law may implicate the information blocking regulations. This FAQ provides two examples of laws where non-compliance by an actor may implicate the information blocking regulations.

Example 1 – ADT Notifications

In the Centers for Medicare & Medicaid Services (CMS) Interoperability and Patient Access Final Rule (85 FR 25510, 25602-03), CMS modified the Conditions of Participation (CoPs) to require hospitals (42 C.F.R. § 482.24(d)), psychiatric hospitals (42 C.F.R. § 482.61(f)), and critical access hospitals (CAHs) (42 C.F.R. § 485.638(d)) to send electronic patient event notifications of a patient's admission, discharge, and transfer (ADT) to another health care facility or to another provider or practitioner ("ADT notifications"). The CMS regulations do not require such hospitals to first receive a request for access, exchange, or use of EHI for the obligation to send the ADT notification to be triggered. Thus, if a hospital (an "actor" under 45 CFR 171.102) does not comply with the regulatory requirement to send the ADT notification, its noncompliance could be an interference with the access, exchange, or use of EHI under the information blocking regulations.

Example 2 – Public Health Reporting

Where a law requires actors to submit EHI to public health authorities, an actor's failure to submit EHI to public health authorities could be considered an interference under the information blocking regulations. For example, many states legally require reporting of certain diseases and conditions to detect outbreaks and reduce the spread of disease. Should an actor that is required to comply with such a law fail to report, the failure could be an interference with access, exchange, or use of EHI under the information blocking regulations.

Please see the following FAQ for more information on how practices would be evaluated to determine whether the unique facts and circumstances constitute information blocking: **Q: How would any claim or report of information blocking be evaluated? (IB.FAQ46.1.2022FEB)**

Information Blocking – General

Q: How would any claim or report of information blocking be evaluated? (IB.FAQ46.1.2022FEB)

A: The facts and circumstances of each situation or allegation would need to be evaluated. Whether a practice constitutes information blocking depends on the unique facts and circumstances of the practice. More specifically, information blocking occurs when: an individual or entity engaging in a practice is an actor as defined in 45 CFR 171.102; the practice involves EHI as defined in 45 CFR 171.102; the actor meets the requisite knowledge standard applicable to the type of actor; the practice is likely to prevent, materially discourage, or otherwise inhibit the access, exchange, or use of EHI; the practice is not one that is required by law; and the practice is not covered by an exception under 45 CFR Part 171.

Preventing Harm Exception

Q: In which patient access cases does the Preventing Harm Exception recognize "substantial harm" [3] ? (IB.FAQ42.1.2022FEB)

A: The Preventing Harm Exception at 45 CFR 171.201 relies on the same types of harm as apply for a covered entity to deny access to protected health information under the HIPAA Privacy Rule (see 45 CFR 164.524(a)(3)). Where an actor's practice, based on an individualized (45 CFR 171.201(c)(1)) determination of risk, is likely to interfere with a patient's or patient representative's access, exchange, or use of the patient's EHI, the type of harm (45 CFR 171.201(d)) needed for the exception to apply depends on who is seeking access to the EHI, and what EHI they are seeking to access.[4]

The table below shows the *type of harm* recognized under the Preventing Harm Exception for several commonly encountered patient access scenarios.[1]

Access, exchange, or use of patient's EHI	**EHI for which access, exchange, or use is affected by the interfering practice is**	**Applicable type of harm**[1]	**Regulation Text References**
Patient exercising own right of access	Patient's EHI	Danger to life or physical safety of the patient or another person	§ 171.201(d)(3), referencing HIPAA Privacy Rule § 164.524(a)(3)(i)

Access, exchange, or use of patient's EHI	EHI for which access, exchange, or use is affected by the interfering practice is	Applicable type of harm[1]	Regulation Text References
	Patient's EHI that references another person	Substantial harm[3] to such other person	§ 171.201(d)(2), referencing HIPAA Privacy Rule § 164.524(a)(3)(ii)
Patient's personal representative as defined in HIPAA Privacy Rule (45 CFR 164.502) exercising right of access to patient's EHI *(for example, parent of a minor child)*[2]	Patient's EHI	Substantial harm[3] to the patient or to another person	§ 171.201(d)(1), referencing HIPAA Privacy Rule § 164.524(a)(3)(iii)
	Patient's EHI that references another person	Substantial harm[3] to such other person	§ 171.201(d)(2), referencing HIPAA Privacy Rule § 45 CFR 164.524(a)(3)(ii)

Notes:

1 - For simplicity of presentation, this table focuses only on patient access use case examples where risk has been determined on an individual basis (45 CFR 171.201(c)(1)). Where the risk arises from data that is known or reasonably suspected to be misidentified or mismatched, corrupt due to technical failure, or erroneous for another reason (45 CFR 171.201(c)(2)), the exception's applicable type of harm conditions (45 CFR 171.201(d)(3) and (4)) recognize only danger to life or physical safety of the patient or another person.

2 - For more information about the definition of a "personal representative" under the HIPAA Privacy Rule, please see https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/personal-representatives/index.html

3 - "Substantial harm" includes "substantial physical, emotional, or psychological harm" (see, for example, *HIPAA Privacy Rule preamble at 65 FR 82556).*

Access, exchange, or use of patient's EHI	EHI for which access, exchange, or use is affected by the interfering practice is	Applicable type of harm[1]	Regulation Text References
4 - In order for the Preventing Harm Exception to cover any practice likely to interfere with access, exchange, or use of EHI based on an individualized (45 CFR 171.201(c)(1)) determination of risk, the practice must also satisfy requirements in 45 CFR 171.201(a), (b), (e), and (f).			

For more information about the Preventing Harm Exception, please reference the ONC Cures Act Final Rule preamble discussion and the other FAQs under the Preventing Harm Exception heading.

For more information about the HIPAA Privacy Rule, the Privacy Rule individual right of access, or grounds for denial of access under the Privacy Rule, please visit the Health Information Privacy section of the HHS website.